natural gas in the United States have not been available and that this additional supply of natural gas is necessary to meet the increasing fuel requirements of its customers. Applicant states that the price of the LNG to be imported will be $83 per metric ton, which will be the equivalent of approximately $1.70 per Mcf.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 15 days for the filing or protests and petitions to intervene. Therefore, any person desiring to be heard or to make any protest with reference to said application should on or before May 3, 1971, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

KENNETH F. PLUMB,
Acting Secretary.

[FR Doc.71-5712 Filed 4-23-71;8:45 am]

[Docket No. CP71-241]

MISSISSIPPI RIVER TRANSMISSION CORP.

Notice of Application

APRIL 20, 1971.

Take notice that on April 9, 1971, Mississippi River Transmission Corp. (applicant), 9900 Clayton Road, St. Louis, MO 63124, filed in Docket No. CP71-241 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain natural gas loopline facilities and a new delivery point to an existing resale customer, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, applicant seeks authorization to construct and operate 26.5 miles of 26-inch pipeline loops, in eight different sections, of its existing Main Line System in Arkansas and Missouri, together with minor piping and facility changes at certain compressor stations on said System. Applicant also seeks authorization to construct and operate a new delivery point, near St. Louis, Mo., to an existing resale customer, Midwest Missouri Gas Co.

Applicant states that the facilities proposed herein are required to maintain operating flexibility, to meet emergency situations and to overcome loss of deliverability due to reductions of operating pressures on a portion of its Main Line No. 1. The estimated cost of the facilities proposed herein is $3,996,000, which cost applicant states will be financed by internally generated funds and interim bank loans.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 11, 1971, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdicion conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Acting Secretary.

[FR Doc.71-5713 Filed 4-23-71;8:45 am]

[Docket No. CP71-246]

SOUTHERN NATURAL GAS CO.

Notice of Application

APRIL 20, 1971.

Take notice that on April 12, 1971, Southern Natural Gas Co. (applicant), Post Office Box 2563, Birmingham, AL 35202, filed in Docket No. CP71-246 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain offshore and onshore supply facilities, and the transportation of natural gas for The California Co., a division of Chevron Oil Co. (California), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, applicant proposes to construct and operate approximately 17.1 miles of 14-inch pipeline extending in a generally north by northeastern direction from applicant's Main Pass-South Pass 26-inch pipeline in Main Pass Block 141, offshore Louisiana, to California's production platform in Main Pass Block 107 and related facilities on said platform for the receipt of natural gas purchased from California. Applicant also seeks authorization to construct and operate side valves, block valves and other related facilities onshore in southern Louisiana, to enable applicant to deliver natural gas to California for processing and to accept redelivery of said natural gas after processing. To facilitate this processing, applicant seeks authorization to transport natural gas for plant use, fuel, loss, and shrinkage from the delivery point in Block 107 to the onshore processing plant.

The estimated cost of the facilities proposed herein is $3,307,410, which cost applicant states will be financed by the use of cash on hand.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 10, 1971, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Acting Secretary.

[FR Doc.71-5714 Filed 4-23-71;8:46 am]

[Docket No. E-7172]

SOUTHWESTERN POWER ADMINISTRATION, DEPARTMENT OF THE INTERIOR

Notice of Request for Approval of Rates and Charges

APRIL 20, 1971.

Notice is hereby given that the Secretary of the Interior, acting on behalf

of Southwestern Power Administration (SWPA), has filed with the Federal Power Commission, pursuant to section 5 of the Flood Control Act of 1944 (58 Stat. 887, 890), a request in the above-entitled proceeding for confirmation and approval of certain rate schedules and certain changes in contractual rates and charges applicable to the sale of electric power and energy from the integrated system of SWPA for a period of 3 years beginning June 1, 1971 and ending May 31, 1974. Approval by the Commission of SWPA's rate schedules and contractual rates and charges currently applicable to the sale of such power and energy expires May 31, 1971 in accordance with the Commission's order issued May 28, 1970, Docket No. E-7172 (43 FPC 804), and the Commission's letter dated December 4, 1970, Docket No. E-7579, to the Assistant Secretary of the Interior.

SWPA seeks Commission approval of the following rate schedules, which contain the same terms, conditions, and provisions as the currently approved rate schedules referred to above:

Rate Schedule F-1—Wholesale Firm Power Service. Demand charge: $1.60 per kw. of monthly billing demand. Energy charges: 2 mills per kw.-hr. for the first 150 kw.-hr. per kw. of billing demand, and 3 mills per kw.-hr. for the next 290 kw.-hr. per kw. of billing demand, and 5 mills per kw.-hr. for energy in excess of 440 kw.-hr. per kw. of billing demand.

Rate Schedule IC. This schedule is for interruptible capacity at such times and amounts as SWPA determines is available. The capacity charge is $0.45 per kw. per day and at SWPA's election, energy may be sold at $0.002 per kw.-hr. or returned by customer as scheduled by SWPA.

Rate Schedule EE. This schedule is for excess energy at such times and in such amounts as SWPA determines is available. The rate is $0.0015 per kw.-hr.

Rate Schedule P2 (Revised). This schedule for hydro peaking and seasonal peaking power represents the main transmission grid rate. This schedule provides for delivery of power from and at the voltage of 138-kv. or 161-kv. transmission systems owned by SWPA and/or a substation owned by SWPA that is directly connected to 138-kv. and/or 161-kv. transmission facilities owned by SWPA, or beyond the high voltage grid as specified by contract. The minimum amount of energy associated with service under this schedule shall be 1,200 kw.-hr. per kv. of demand during each 12-month contract-year, with the annual demand charge of $14.40 per kw. and energy charge at $0.002 per kw.-hr. The minimum bill shall be $1.20 per month per kw. of Peaking Contract Demand, plus the transmission service charge, if any. This schedule also provides that where transmission service is provided beyond the SWPA high voltage grid and SWPA incurs additional costs therefor (such as payment, credit, or the construction of Federal facilities), the customer shall pay in addition to the demand and energy charges, a separate Transmission Service Charge each month equal to one-twelfth of the estimated total annual cost to SWPA of providing such transmission service. The amount of such total annual cost shall be computed and determined by SWPA, and a memorandum copy of each such determination shall be attached to and become a part of this schedule.

Rate Schedule ES. This schedule is for emergency service. The energy charge is 3.7 mills per kw.hr. The capacity charge is 4.5 cents per kw. per day. This schedule is available in SWPA's service area to those who were wholesale power customers of SWPA as of November 30, 1970.

SWPA also seeks Commission approval to increase the rates and charges contained in SWPA's (1) contract with Oklahoma Gas and Electric Co. and Public Service Company of Oklahoma (Oklahoma Companies), designated as Contract Ispa-356, and (2) contract with Southwestern Electric Power Co. (Southwestern Electric), designated as Contract 14-02-001-782, which rates and charges are the currently approved contractural rates and charges referred to above. More specifically, SWPA proposes that the energy charge to the Oklahoma Companies be increased from $0.002 per kw.hr. to $0.0034 per kw.hr. for each kw.hr. scheduled and received by the Oklahoma Companies during each month. SWPA represents that the new and higher energy charge to the Oklahoma Companies is comprised of two components, namely, $0.002 being related to the cost of energy production and transmission, and $0.0014 being related to the "Service Charge Component". SWPA also proposes that the energy charge to Southwestern Electric be increased from $0.002 per kw.hr. to $0.0029 per kw.hr. for energy delivered by SWPA to Southwestern Electric. SWPA represents that the new and higher energy charge to Southwestern Electric is comprised of two components, namely, $0.002 being related to the cost of energy production and transmission, and $0.0009 being related to the "Service Charge Component".

The proposed rate schedules and proposed changes in contractual rates and charges described above, together with the repayment study in support thereof, are on file with the Commission and available for public inspection. Any person desiring to make comments or suggestions for the Commission's consideration with respect to the proposed rate schedules or proposed changes in contractural rates and charges should submit the same in writing on or before May 10, 1971, to the Federal Power Commission, Washington, D.C. 20426.

KENNETH F. PLUMB,
Acting Secretary.

[FR Doc.71-5715 Filed 4-23-71;8:46 am]

GENERAL SERVICES ADMINISTRATION

[Temporary Reg. D-28]

SECRETARY OF DEFENSE

Delegation of Authority

1. *Purpose.* This regulation delegates authority to the Secretary of Defense to assist in controlling vehicular and pedestrian traffic on that part of Fort George G. Meade, Md., that is occupied by the National Security Agency.

2. *Effective date.* This regulation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949 (63 Stat. 377), as amended, and the Act of June 1, 1948 (62 Stat. 281), as amended, authority is hereby delegated to the Secretary of Defense to make all needful rules and regulations, and to annex to such rules and regulations such reasonable penalties, not to exceed those prescribed in 40 U.S.C. 318c, as will insure their enforcement, for governing vehicular and pedestrian traffic on the property, buildings, and parking lots used by the National Security Agency at Fort George G. Meade, Md., over which the United States has exclusive legislative jurisdiction.

b. The Secretary of Defense may redelegate this authority to any officer or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the limitations and requirements of the above cited Acts, and the policies, procedures, and controls prescribed by the General Services Administration.

ROD KREGER,
Acting Administrator of General Services.

APRIL 16, 1971.

[FR Doc.71-5708 Filed 4-23-71;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

BROKERAGE DATA PROCESSING CORP.

Order Suspending Trading

APRIL 19, 1971.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Brokerage Data Processing Corp., a New York corporation, and all other securities of Brokerage Data Processing Corp. being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

It is ordered, Pursuant to section 15(c)(5) of the Securities Exchange Act

of 1934, that trading in such securities otherwise than on a national securities exchange be summarily suspended, this order to be effective for the period April 19, 1971, through April 28, 1971.

By the Commission.

[SEAL] ROSALIE F. SCHNEIDER,
Recording Secretary.

[FR Doc.71-5723 Filed 4-23-71;8:46 am]

[70-5010]

COLUMBIA GAS SYSTEM, INC., ET AL.

Notice of Proposed Intrasystem Financing

APRIL 19, 1971.

In the matter of the Columbia Gas System, Inc., 20 Montchanin Road, Wilmington, DE 19807, Columbia Gas of West Virginia, United Fuel Gas Co., Atlantic Seaboard Corp., Columbia Gas of Kentucky, Inc., Columbia Gas of Virginia, Inc., Kentucky Gas Transmission Corp., Columbia Gas of Ohio, Inc., the Ohio Fuel Gas Co., the Ohio Valley Gas Co., the Preston Oil Co., Columbia Gas of Pennsylvania, Inc., the Manufacturers Light and Heat Co., Home Gas Co., Columbia Gas of New York, Inc., Columbia Gas of Maryland, Inc., Columbia Coal Gasification Corp., Columbia Gulf Transmission Co., Columbia Gas Development Corp.

Notice is hereby given that The Columbia Gas System, Inc. (Columbia), a registered holding company, and its above-named wholly owned subsidiary companies (hereinafter referred to as "Columbia of W. Va.," "United Fuel," "Seaboard," "Columbia of Ky.," "Columbia of Va.," "Kentucky Gas," "Columbia of Ohio," "Ohio Fuel," "Ohio Valley," "Preston," "Columbia of Pa.," "Manufacturers," "Home," "Columbia of N.Y.," "Columbia of Md.," "Coal Gasification," "Columbia Gulf," and "Columbia Development") have filed an application-declaration and an amendment thereto with this Commission pursuant to the Public Utility Holding Company Act of 1935 (Act), designating sections 6(a), 6(b), 7, 9(a), 10, 12(b), and 12(f) of the Act and Rules 43 and 45 promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the application-declaration, which is summarized below, for a complete statement of the proposed transactions.

The subsidiary companies propose to issue and sell, and Columbia proposes to acquire, prior to April 1, 1972, (a) unsecured installment notes not in excess of the respective amounts set forth below and (b) common stock, at the par value, in the respective amounts set forth below. Columbia also proposes to advance an open account to certain of the subsidiary companies, from time to time during 1971, up to the respective amounts set forth below:

	Advances	Common stock	Installment notes
Columbia of W. Va.	$3,100,000	$4,300,000	
United Fuel	11,200,000	16,000,000	$37,275,000
Seaboard	1,100,000	1,000,000	4,575,000
Columbia of Ky	2,100,000	1,000,000	1,150,000
Columbia of Va	600,000		425,000
Kentucky Gas	200,000		
Columbia of Ohio	18,400,000		15,000,000
Ohio Fuel	23,500,000		8,000,000
Ohio Valley	1,100,000		1,400,000
Preston		1,600,000	1,800,000
Columbia of Pa	4,200,000		6,100,000
Manufacturers	6,700,000		8,800,000
Columbia of N.Y.	600,000		
Columbia of Md	300,000		375,000
Home	2,900,000		2,000,000
Columbia Gulf			15,500,000
Columbia Development		3,000,000	4,000,000
Coal Gasification		4,075,000	
Total	76,000,000	30,975,000	106,400,000

The subsidiary companies will use the proceeds from the issue and sale of their notes and common stock to finance a part of their respective construction programs, which, in the aggregate, are estimated for 1971 to require expenditures of $216,837,400. The proceeds of the open account advances will be used by the subsidiary companies to finance the purchase of undeground storage gas inventories and miscellaneous other inventories and for short-term seasonal purposes.

The installment notes will be acquired no later than March 31, 1972, will be dated when issued, will be payable in 25 equal annual installments on May 31 of each of the years 1973–97, inclusive, and may be prepaid at any time, in whole or in part, without premium. Interest will accrue from the date of issue and is to be paid semiannually on the unpaid principal balance. The interest rate will be the actual cost of money to Columbia with respect to its last sale of debentures prior to the issuance of said notes, decreased by an amount necessary in order that the interest rate be a multiple of one-tenth of 1 percent.

The open account advances will be made from time to time during 1971 and will be paid by the subsidiary companies in three equal installments on February 25, March 24, and April 25, 1972. The open account advances will initially bear interest at the prime commercial bank rate in effect from time to time. The interest charges will be adjusted, after the storage financing period, to the effective interest cost Columbia achieves on its short-term borrowing for this purpose.

In order to meet current cash requirements of Columbia of W. Va., Columbia also proposes (1) to make a cash capital contribution of $5,600,000, (2) to forgive interest on all debts of Columbia of W. Va. as it becomes due and payable to Columbia on or before March 31, 1972, in an amount up to $2,100,000, and (3) to defer the payment of installment debt maturities due from Columbia of W. Va. and to consider such maturities due the year following the last installment due under each issue.

An order has been issued by the Commission dated March 18, 1971 (Holding Company Act Release No. 17055), authorizing the merger of United Fuel, Seaboard, Ohio Fuel, Manufacturers, Kentucky Gas, and Home into Columbia Gas Transmission Corp. Columbia anticipates that said merger will be consumated as at July 1, 1971, and it is requested that authorizations granted herein with respect to these individual transmission companies be extended to Columbia Gas Transmission Corp. to the extent that approved financing has not been consummated with respect to the individual corporations at the date of merger.

The expenses to be paid by Columbia and by the subsidiary companies in connection with the proposed transactions are estimated at $400 and $6,900, respectively.

The application-declaration states that the following State commissions have jurisdiction over certain of the proposed transactions: the Pennsylvania Public Utility Commission, the Public Service Commission of West Virginia, the Public Utilities Commission of Ohio, the State Corporation Commission of Virginia, the Kentucky Public Service Commission, and the New York Public Service Commission. It is also stated that the orders of said commissions will be filed with this Commission by amendment. No other State commission and no Federal commission, other than this Commission, is stated to have jurisdiction over the proposed transactions.

Notice is further given that any interested person may not later than May 6, 1971, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the filing which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail (airmail if the person being served is located more than 500 miles from the point of mailing) upon the applicants-declarants at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as amended or as it may be further amended, may be granted and permitted to become effective as provided in Rule 23 of the general rules and regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive notice of further developments in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

[SEAL] ROSALIE F. SCHNEIDER,
Recording Secretary.

[FR Doc.71-5722 Filed 4-23-71;8:46 am]

[811-529]

MISSOURI-KANSAS PIPE LINE CO.

Notice of Filing of Application for Declaring Company Has Ceased To Be an Investment Company

APRIL 19, 1971.

Notice is hereby given that Missouri-Kansas Pipe Line Co. (Applicant), 25 Broadway, New York, NY 10004, a Delaware corporation registered under the Investment Company Act of 1940 (Act), as a closed-end nondiversified management investment company, has filed an application pursuant to section 8(f) of the Act for an order of the Commission declaring that Applicant has ceased to be an investment company as defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein which are summarized below.

On March 19, 1971, the respective shareholders of Applicant and of Panhandle Eastern Pipe Line Co. (Panhandle) duly authorized the merger of Applicant into Panhandle, a Delaware corporation, and it is expected that on April 19, 1971, the Agreement of Merger of Applicant into Panhandle will be filed with the appropriate State agency whereupon the merger will become effective. Pursuant to the terms of the merger, each holder of Applicant's common stock or class B stock, or both, will receive shares of Panhandle common stock determined by a formula based on the market price of Panhandle stock and the value of the net Mokan assets. Each shareholder of Applicant will be entitled to exchange his existing certificate or certificates for a certificate or certificates representing common stock of Panhandle (and cash in lieu of fractional Panhandle shares) by presenting such certificate or certificates to The Corporation Trust Co., 15 Exchange Place, Jersey City, NJ, the exchange agent. Applicant represents that its separate existence as an investment company will terminate on the date the merger becomes effective and that Panhandle, the surviving corporation in the merger, will become vested with all the property, rights, privileges, powers, and franchises of Applicant on that date.

Section 8(f) of the Act provides, in pertinent part, that when the Commission, upon application, finds that a registered investment company has ceased to be an investment company, it shall so declare by order, and upon the effectiveness of such order the registration of such company shall cease to be in effect, and that, if necessary for the protection of investors, such order may be made upon appropriate conditions.

Notice is further given that any interested person may, not later than May 6, 1971, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission should order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail (airmail if the person being served is located more than 500 miles from the point of mailing) upon the Applicant at the address stated above. Proof of such service (by affidavit or in case of an attorney at law by certificate) shall be filed contemporaneously with the request. At any time after said date, as provided by Rule 0-5 of the rules and regulations promulgated under the Act, an order disposing of the application herein may be issued by the Commission upon the basis of the information stated in said application, unless an order for hearing upon said application shall be issued upon request or upon the Commission's own motion. Persons who request a hearing or advice as to whether a hearing is ordered will receive notice of further developments in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

[SEAL] ROSALIE F. SCHNEIDER,
Recording Secretary.

[FR Doc.71-5724 Filed 4-23-71;8:46 am]

INTERSTATE COMMERCE COMMISSION

[Rev. S.O. No. 994; ICC Order No. 55, Amdt. 1]

CENTRAL RAILROAD COMPANY OF NEW JERSEY

Rerouting or Diversion of Traffic

Upon further consideration of ICC Order No. 55 (The Central Railroad Company of New Jersey, R. D. Timpany, Trustee) and good cause appearing therefor:

It is ordered, That:

ICC Order No. 55 be, and it is hereby amended by substituting the following paragraph (g) for paragraph (g) thereof:

(g) *Expiration date.* This order shall expire at 11:59 p.m., June 30, 1971, unless otherwise modified, changed or suspended.

It is further ordered, That this amendment shall become effective at 11:59 p.m., April 23, 1971, and that this order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and per diem agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that it be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., April 20, 1971.

INTERSTATE COMMERCE COMMISSION,
[SEAL] R. D. PFAHLER,
Agent.

[FR Doc.71-5747 Filed 4-23-71;8:48 am]

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PART II

DEPARTMENT OF JUSTICE

Bureau of Narcotics and Dangerous Drugs

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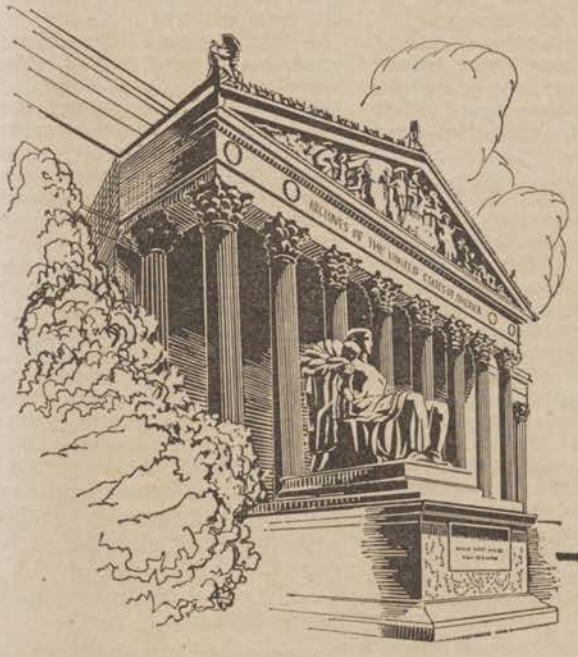
REGULATIONS IMPLEMENTING THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970



Title 21—FOOD AND DRUGS

Chapter II—Bureau of Narcotics and Dangerous Drugs, Department of Justice

REGULATIONS IMPLEMENTING THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

A notice was published in the FEDERAL REGISTER of March 13, 1971 (36 F.R. 4928) proposing regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970.

In response, a substantial number of comments were received from members of the drug industry through the American Medical Association, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the Pharmaceutical Manufacturers Association, the National Wholesale Druggists Association, the Pharmaceutical Wholesalers Association, the National Association of Retail Druggists, and from many individuals and corporations.

COMMENTS AND OBJECTIONS TO PART 301

1. Various persons, including the American Medical Association and the Pharmaceutical Manufacturers Association, inquired whether agents and employees of registrants were required to register individually. Section 301.24 was revised to clarify the fact that they are generally not required to register.

2. Many manufacturers, through the Pharmaceutical Manufacturers Association and individually, inquired whether separate registrations were necessary to conduct quality control analysis and other activities related to manufacturing. Section 301.22(b) was revised to state what activities are authorized under the registration of a manufacturer.

3. Several persons inquired as to the authority of a person other than an officer of a corporation signing application forms and order form powers of attorney for a corporation. Section 301.32(f) was revised to permit this alternative on the condition that a corporate officer notify the Bureau as to the authority of the other person.

4. Several manufacturers objected to the inclusion of § 301.43(b). The Director, after reviewing the objections and meeting with representatives of various interested groups, has concluded that this paragraph is properly included in the regulations, particularly in light of the legislative history of the Controlled Substances Act and the change in language in section 303(a)(1) of the Act from the earlier language found in section 8(a)(1) of the Narcotics Manufacturing Act of 1960.

5. The Pharmaceutical Manufacturers Association and Pfizer, Inc., questioned the ambiguity in § 301.55 (a) and (b) regarding persons entitled to an administrative hearing. This language was revised to point out who could request, or participate in, such hearings under Part 301.

6. Many manufacturers and distributors objected to security controls set forth in §§ 301.91 to 301.97. Most of these paragraphs have been revised to meet the objections filed. Sections 301.92 and 301.93 are not being published at this time, however, pending further discussions between the Bureau and members of the industry. Physical security requirements for nonpractitioners will be published in the near future.

COMMENTS AND OBJECTIONS TO PART 302

1. Several manufacturers, through the Pharmaceutical Manufacturers Association and individually, objected to the size of the symbol required on a label and to the requirement of the overprinting of the symbol on substances listed in schedule V. The Director has concluded that the requirement of overprinting is not necessary for schedule V substances and section 302.04 has been revised accordingly. After reviewing the comments on the size symbol on the label, however, the Director believes that as a general rule the symbol should be at least two times of the largest type otherwise printed on the label. In cases where this is not practicable, manufacturers should apply for an exception from this requirement pursuant to § 307.03, submitting a copy of the existing label and a draft of the proposed label.

2. Several manufacturers, including the Pharmaceutical Manufacturers Association, commented that the language in § 302.06 (a) and (b), regarding the effective dates of labeling requirements, was unclear. This language has been revised to clearly state that the labeling requirements apply only to containers packaged after the effective date set forth in each paragraph.

3. Several manufacturers inquired as to the effective date of the sealing requirements contained in Section 302.07. This section shall be effective on May 1, 1971. Any manufacturer who cannot comply on this effective date should file a request for an exception under § 307.03, including the date on which compliance can be achieved.

COMMENTS AND OBJECTIONS TO PART 303

1. Several manufacturers, including Mallinckrodt Chemical Works and Wyeth Laboratories, suggested that the Bureau return to the quota system utilized under the Narcotics Manufacturing Act of 1960. The Director, after reviewing their comments, realizes the system proposed probably will lead to lesser accuracy because of longer range estimates, and more administrative activity to revise quotas as estimates are revised, than the former system. The Director has concluded, however, that the advantages of setting quotas in advance of the year in which the quota is to become effective outweighs these disadvantages. The Director anticipates that adjustments to this system will be required as experience is gained.

2. The American Medical Association urged the Director to consult with recognized medical and scientific authorities in determining aggregate production quotas. The Director will, under section 701(j) of the Act, receive the advice of the Surgeon General of the United States on these matters. In addition, the Director anticipates consulting with other members of the medical community in individual cases in determining such quotas.

3. Several manufacturers requested changes in the procedures for fixing individual manufacturing quotas if the proposed quota system were retained, in order to make the adjustments necessary when estimates are found to be wrong and in order to accommodate special production problems. The regulations have been revised in light of their suggestions.

COMMENTS AND OBJECTIONS TO PART 304

1. The National Association of Chain Drug Stores proposed that special permission be allowed for central record keeping. After discussions with this group, the Bureau has revised § 304.04(a) to permit, under certain conditions, keeping of certain records at a central location.

2. Several manufacturers pointed out that many labels still list weight in avoirdupois units rather than metric units. Section 304.15 was revised to permit 1971 inventories to show avoirdupois weight.

3. Many persons and organizations, including the National Association of Wholesale Druggists, the Pharmaceutical Wholesalers Association, the National Association of Retail Druggists, and the National Association of Chain Drug Stores, objected to the inclusion on an inventory of the total quantity of a substance in all forms in metric weight. After receiving these objections, the Director has concluded that the requirement is not necessary and § 304.15(c)(5) has been deleted.

4. Many groups representing retail-pharmacies urged that in taking an inventory of substances listed in schedules III, IV, and V, an estimated count should satisfy. The Director has concluded that the risk of error is small enough to permit estimates when containers hold no more than 1,000 tablets or capsules; in larger containers, however, an exact count is still required.

5. Comments on the reporting requirements were received from the Pharmaceutical Manufacturers Association, the Pharmaceutical Wholesalers Association, and the National Wholesale Druggists Association, as well as from other persons, and certain changes were made accordingly. The Director wishes to point out that these requirements are intended to continue existing reporting requirements until a new system of reporting that more fully accords with the Act can be designed and implemented. It is anticipated that this will require 9 to 12 months and at that time §§ 304.31–304.35 will be replaced.

COMMENTS AND OBJECTIONS TO PART 305

1. An objection was led to the limitation of authorized signatures on an order

form. The purpose is to prevent unauthorized persons from obtaining controlled substances through the use of order forms.

2. The Pharmaceutical Manufacturers Association and Merck and Co., Inc., objected to the 60-day validity limit on order forms. The Director concluded that although a problem might exist, the short time period should be tried. If experience indicates that a significant number of orders are being invalidated by this time limit, the Director, will receive requests for amendment to the rule.

COMMENTS AND OBJECTIONS TO PART 306.

1. The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § 306.04 to determine the legitimacy of a prescription. The language has been revised to require knowledge.

2. Several pharmacy groups protested the requirement under § 306.11(c)(4) that, if a doctor fails to provide an authorization for emergency order as required, the pharmacist must so report to the Bureau or be liable for dispensing a substance in schedule II without a written prescription. The Director considered the problems and concluded that only this mechanism assures information to the Bureau about doctors who refuse to comply with the Act.

3. The American Pharmaceutical Association and the National Association of Chain Drug Stores suggested that, in the case of a partial filling of a schedule II substance, the pharmacist notify the doctor only when the remainder cannot be filled, in order for the doctor to issue a new prescription. The language was revised accordingly.

4. All retail druggist associations urged revision in the labeling requirements for prescriptions set forth in §§ 306.14 and 306.23. In response, the Director has had the requirements of inclusion of the patient's address and the doctor's registration number deleted.

5. In response to a comment from the National Association of Retail Druggists, a definition of prescription was added which covers all orders for medication except hospital orders (i.e., orders for medication to be administered immediately and cannot be removed from the hospital either by an out-patient or by an in-patient being discharged). Sections 306.11, 306.21, and 306.31 were revised to indicate that institutional practitioners (e.g., hospitals) can only dispense by prescription or hospital order.

6. Several questions were asked about the status of paregoric. This is a schedule III substance which is not now a prescription drug under the Food, Drug, and Cosmetic Act and therefore not subject to the prescription requirements of the Controlled Substances Act. Until such time as it becomes a prescription drug, the Director has determined to treat it in the same manner as a schedule V substance. Section 306.32 has been revised accordingly.

COMMENTS AND OBJECTIONS TO PART 307

The Pharmaceutical Manufacturers Association suggested substitution of some synonym for "disposal" and elimination of restrictions on the destruction of controlled substances set forth in §§ 307.21 and 307.22. After considering these suggestions, the Director has concluded that "dispose" is the best word and that the restrictions are necessary. For persons who regularly destroy controlled substance, the Director suggests an application for an exception under § 307.03, including details of the procedures followed and provisions for notice to the Bureau.

COMMENTS AND OBJECTIONS TO PART 308

1. Several manufacturers, through the Pharmaceutical Manufacturers Association and individually, raised questions concerning the function of the Bureau Controlled Substances Code Number. Section 308.03 has been included to set this forth.

2. Mallinckrodt Chemical Works pointed out that the lack of language in § 308.14(b) made it appear that salts of schedule IV substances were in schedule III. This has been corrected to eliminate this confusion.

3. The Pharmaceutical Manufacturers Association and Pfizer, Inc., suggested that no application be required under § 308.21 to exclude a substance from control under section 201(g) of the Act. The Director has concluded that such a change would create greater administrative and legal difficulties in handling such substances than the procedure proposed.

4. A number of manufacturers inquired about individual compounds excepted in § 308.32. This list contains only some of the excepted compounds; those previously excepted as being similar to this list and not listed continue to be expected.

COMMENTS AND OBJECTIONS TO PART 311

Several manufacturers objected strongly to the proposed § 311.42 (b), (c). The Director has reviewed their comments carefully, as well as the comments of the Antitrust Division of the Department of Justice, and has discussed this matter extensively with the firms concerned. After considerable analysis, the Director has concluded that the paragraphs should be retained, with several modifications that emphasize noncompetitive factors to be considered in registering an importer and other factors that affect competition. The standards set forth for determining the adequacy of competition are not exclusive and leave the Bureau with flexibility to consider additional factors in special cases. The factors enumerated, however, focus attention on several of the most important measures of competitive performance and are based on well recognized economic analysis. In particular, the element of substantial differentials between foreign and domestic prices is included because foreign prices provide the only marketplace yardstick available to appraise the efficiency of domestic producers. Substantial differentials, not accounted for by particular factors (such as cost of security requirements, imposed by the Controlled Substances Act), evidence of either excessive profits or inefficient operations, or both, and an absence of adequate competition among domestic manufacturers.

The Director emphasized that the Bureau, by adopting § 311.42, has no intention of lowering its strict requirements of security and safeguards against diversion, and that any prospective importer will be required to show that he maintains effective controls against diversion throughout the process of importation.

COMMENTS AND OBJECTIONS TO PART 312.

1. The Pharmaceutical Manufacturers Association suggested that alternative ports of exportation in different countries be permitted in applications for import permits under § 312.12(b). The purpose of the permit is, in part, to inform the government of the exporting country that importation is authorized; by having more than one potential exporting country listed, the notice to the exporting country is confusing.

2. The Pharmaceutical Manufacturers Association also suggested that § 312.29 be revised to state that release of a shipment to a bonded shipper was proof of adequate security. The Director does not believe that the needs of preventing diversion of controlled substances can be satisfied by a bond to pay in the event of diversion. The burden remains on the exporter to select a carrier that will provide adequate security.

COMMENTS AND OBJECTIONS TO PART 316.

1. The American Medical Association suggested that medical diagnosis and therapy records be excluded from inspection under § 316.04. The Director is reviewing this request.

2. The American Medical Association and the Pharmaceutical Manufacturers Association suggested coordination between the Bureau and the Secretary of Health, Education, and Welfare on jurisdiction and procedures for granting confidentiality to researchers under § 316.21. The Bureau is discussing this matter with the Department of Health, Education, and Welfare.

OTHER COMMENTS AND OBJECTIONS.

Numerous other objections and comments were received, the majority of which were valid and incorporated into the regulations. Others resulted from a misinterpretation of the language of the proposed regulations, and in many cases the language was revised to state more clearly the intent of the Bureau. In a few cases not discussed here the Director did not accept the position of the party.

The Director has instructed the Office of Chief Counsel of the Bureau to reply to each person who filed comments and respond fully to his comments.

Therefore, under the authority vested in the Attorney General by sections 201 (a), 201(g), 202(d), 301, 302(f), 304, 305, 306(f), 307, 308, 501(b), 505, 507, 511, 513, 704(c), 705, 1002, 1003, 1004, 1006, 1007 (b), 1008(d), 1008(e), and 1015 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and redelegated to the Director, Bureau of Narcotics and Dangerous Drugs, by section 0.100 of

Title 28 of the Code of Federal Regulations, the Director hereby orders that Parts 301, 302, 303, 305, 306, 307, 315, 316, 319, 320, and 330 of Title 21 of the Code of Federal Regulations, and Parts 150, 151, and 152 of Title 26 of the Code of Federal Regulations, be rescinded and replaced with the following:

Part 301—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.
Part 302—Labeling and Packaging Requirements for Controlled Substances.
Part 303—Quotas.
Part 304—Records and Reports of Registrants.
Part 305—Order Forms.
Part 306—Prescriptions.
Part 307—Miscellaneous.
Part 308—Schedules of Controlled Substances.
Part 309—[Reserved]
Part 310—[Reserved]
Part 311—Registration of Importers and Exporters of Controlled Substances.
Part 312—Importation and Exportation of Controlled Substances.
Part 313—[Reserved]
Part 314—[Reserved]
Part 315—[Reserved]
Part 316—Administrative Functions, Practices, and Procedures.

PART 301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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AUTHORITY: The provisions of this Part 301 issued under secs. 301, 302, 303, 304, 501 (b), 505, 507, 84 Stat. 1253, 1254, 1255, 1256, 1271, 1272, 1273; 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

GENERAL INFORMATION

§ 301.01 Scope of Part 301.

Procedures governing the registration of manufacturers, distributors, and dispensers of controlled substances pursuant to sections 301 through 304 of the Act (21 U.S.C. 821–824) are set forth generally by those sections and specifically by the sections of this part.

§ 301.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "basic class" means, as to controlled substances listed in schedules I and II:

(1) each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 308.11(b) of this chapter;

(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 308.11(c) of this chapter;

(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 308.11(d) of this chapter;

(4) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(ii) Apomorphine;
(iii) Codeine;
(iv) Ethylmorphine;
(v) Hydrocodone;
(vi) Hydromorphone;
(vii) Metopon;
(viii) Morphine;
(ix) Oxycodone;
(x) Oxymorphone;
(xi) Thebaine;
(xii) Mixed alkaloids of opium listed in § 308.12(b)(2) of this chapter;
(xiii) Cocaine; and
(xiv) Ecgonine;

(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 308.12(c) of this chapter; and

(6) Methamphetamine, including its salts, isomers, and salts of isomers, when contained in any injectable liquid.

(c) The term "Bureau" means the Bureau of Narcotics and Dangerous Drugs.

(d) The term "Director" means the Director of the Bureau. The Director has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(e) The term "hearing" means any hearing held pursuant to this part for the granting, denial, revocation, or suspension of a registration pursuant to sections 303 and 304 of the Act (21 U.S.C. 823–824).

(f) The term "person" includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(g) The terms "register" and "registration" refer only to registration required and permitted by section 303 of the Act (21 U.S.C. 823).

(h) The term "registrant" means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(i) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

§ 301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice,

Post Office Box 28083, Central Station, Washington, D.C. 20005.

FEES FOR REGISTRATION AND REREGISTRATION

§ 301.11 Fee amounts.

(a) For each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of $50.

(b) For each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of $25.

(c) For each registration or reregistration to dispense, or to conduct research or instructional activities with, controlled substances listed in schedules II through V, the registrant shall pay a fee of $5.

(d) For each registration or reregistration to conduct research or instructional activities with a controlled substance listed in schedule I, the registrant shall pay a fee of $5.

(e) For each registration or reregistration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of $5.

§ 301.12 Time and method of payment; refund.

Registration and reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing. Payment should be made in the form of a personal, certified or cashier's check or money order made payable to "Bureau of Narcotics and Dangerous Drugs." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

§ 301.13 Persons exempt from fee.

(a) The Director shall exempt from payment of a fee for registration or reregistration the following persons:

(1) Any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who is authorized to procure or purchase controlled substances for official use; and

(2) Any official, employee, or other civil officer or agency of the United States, of any State, or any political subdivision or agency thereof, who is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his official duties or employment.

(b) In order to claim exemption from payment of a registration or reregistration fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior certifies to the status and address of the registrant and to the authority of the registrant to preclinical research (including quality acquire, possess, or handle controlled substances.

(c) Exemption from payment of a registration or reregistration fee does not relieve the registrant of any other requirements or duties prescribed by law.

REQUIREMENTS OF REGISTRATION

§ 301.21 Persons required to register.

Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or pursuant to §§ 301.24–301.27. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

§ 301.22 Separate registration for independent activities.

(a) The following eight groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing narcotic and nonnarcotic, and conducting research with nonnarcotic, and conducting instructional activities with narcotic and nonnarcotic, controlled substances listed in schedules II through V;

(4) Conducting research with narcotic controlled substances listed in schedules II through V;

(5) Conducting research and instructional activities with controlled substances listed in schedule I;

(6) Conducting chemical anaysis with controlled substances listed in any schedule;

(7) Importing controlled substances; and

(8) Exporting controlled substance listed in schedules I through IV.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtained a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and control analysis) with narcotic and nonnarcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in schedule I shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the application for registration;

(4) A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered to conduct chemical analysis or instructional activities and to persons exempted from registration pursuant to § 301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered to conduct research with narcotic controlled substances listed in schedules II through V shall be authorized to conduct research with nonnarcotic controlled substances listed in schedules II through V.

(c) A single registration to engage in any group of independent activities may include either (1) one or more controlled substances listed in schedules II through V or (2) one basic class of controlled substance listed in schedule I, except that a registration to conduct chemical analysis may include more than one basic class of controlled substance listed in schedule I and also include one or more controlled substances listed in schedules II through V.

§ 301.23 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registrants other than the registered person or to persons not required to register by virtue of subsection 302(c)(2) of the Act (21 U.S.C. 822(c)(2));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as

samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

§ 301.24 Exemption of agents and employees; affiliated practitioners.

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment. An individual practitioner who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employee or principal practitioner in lieu of being registered himself. (For examples, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered, and a doctor employed by a hospital may administer and dispense, but not issue prescriptions for, controlled substances to patients in the hospital if the hospital is registered to dispense such substances.)

§ 301.25 Exemption of certain military and other personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his official duties. Such officials shall follow procedures set forth in Part 306 of this chapter regarding prescriptions, but shall use the service identification number of the issuing official in lieu of the registration number required on prescription forms.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

§ 301.26 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Bureau, any officer of the U.S. Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with § 316.03(d), or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories must obtain annually a registration to conduct chemcal analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(e) Laboratories of the Bureau shall obtain annually a registration to conduct chemical analysis in accordance with paragraph (d) of this section. In addition to the activities authorized under a registration to conduct chemical analysis pursuant to § 301.22(b)(4), laboratories of the Bureau shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any person, and to import and export such substances in emergencies without regard to the requirements of Part 312 of this chapter if a report concerning the importation or exportation is made to the Distribution Audit Branch of the Bureau within 30 days of such importation or exportation.

§ 301.27 Exemption of civil defense officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within his jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on a special "Civil Defense Emergency Order Form," as described in this section.

(c) Civil Defense Emergency Order Forms shall be furnished by the U.S. Office of Emergency Preparedness and will contain the name of the civil defense or disaster relief organization. Such forms may be used and are valid only during a state of emergency or disaster proclaimed by the President or by a concurrent resolution of the Congress for the area in which the organization using such forms has civil defense or disaster relief jurisdiction, who shall state his position and the nature and legal designation of the emergency or disaster. Such forms may be filled by any person registered under the Act. The organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Act for purposes of recordkeeping pursuant to Part 304 of this chapter.

§ 301.28 Registration regarding ocean vessels.

(a) Controlled substances may be held in medicine chests and dispensaries maintained on board any vessel engaged in international trade or in trade between ocean ports of the United States (including a merchant vessel belonging to the United States) if such substances are purchased by and stored and dispensed under the supervision of:

(1) The medical officer of the owner of the vessel, which officer is (i) Either (*a*) A physician licensed in a State or (*b*) A retired commissioned medical officer of the U.S. Army, Navy, Air Force, Coast Guard, or Public Health Service, and (ii) Is registered under the Act; or

(2) If no medical officer is employed by the owner of such vessel, the master of the vessel, who shall not be registered under the Act and who shall purchase controlled substances only with the approval of, and upon special order forms provided by, a commissioned medical officer of the U.S. Public Health Service.

(b) A medical officer described in paragraph (a) of this section shall obtain registration at the location of the principal office of the owner of the vessel. If he serves as the medical officer for more than one owner of vessels, he shall obtain a separate registration at the location of the principal office of each such owner. Any medical officer shall, in addition to complying with all requirements and duties prescribed for

registrants generally, prepare an annual report as of the date on which his registration expires, which report shall give in detail an accounting for any controlled substances purchased, dispensed or disposed of during the year on behalf of each owner by whom he is employed. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Director.

(c) Owners of vessels described in this section shall not be deemed to possess or dispense any controlled substance purchased, stored and dispensed in accordance with this section.

§ 301.29 Registration regarding commercial aircraft.

(a) Controlled substances may be held for stocking, and be maintained in, medicine chests and first-aid packets on board any aircraft operated by an air carrier under a certificate or permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301) if such substances are purchased by and are stored and dispensed under the supervision of the medical officer of the air carrier, which officer is employed by such air carrier and is registered as a dispenser under the Act. Any air carrier which has more than one principal base of operations and desires to have a medical officer at each such base may, but is not required to, designate more than one medical officer.

(b) Any medical officer described in this section shall, in addition to complying with all requirements and duties prescribed for registrants generally, prepare an annual report as of the date on which his registration expires, which report shall give in detail an accounting for any controlled substances purchased, dispensed or disposed of during the year. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Director.

(c) Air carriers operating aircraft described in this section shall not be deemed to possess or dispense any controlled substance purchased, stored and dispensed in accordance with this section.

APPLICATIONS FOR REGISTRATION

§ 301.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and Certificate of Registration is issued by the Director to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time any person is first registered, he shall be assigned to one of 12 groups, which shall correspond to the months of the year. The expiration date of the registrations of all persons within any group will be the last day of the month designated for that group. In assigning any person to a group, the Bureau may select a group the expiration date of which is less than 1 year from the date such person was registered. If the person is assigned to a group which has an expiration date less than 3 months from the date on which the person is registered, the registration shall not expire until 1 year from that expiration date; in all other cases, the registration shall expire on the expiration date first following the date on which the person is registered.

§ 301.32 Application forms; contents; signature.

(a) If any person is required to be registered, and is not so registered and is applying for registration:

(1) To manufacture or distribute controlled substances, he shall apply on BND Form 225;

(2) To dispense narcotic or nonnarcotic, or to conduct research with nonnarcotic, or to conduct instructional activities with narcotic or nonnarcotic, controlled substances listed in schedules II through V, he shall apply on BND Form 224;

(3) To conduct research with narcotic controlled substances listed in schedules II through V, he shall apply on BND Form 225;

(4) To conduct research with a controlled substance listed in schedule I, he shall apply on BND Form 225, with three copies of a research protocol describing the research project attached to the form;

(5) To conduct instructional activities with a controlled substance listed in schedule I, he shall apply as a researcher on BND Form 225 with two copies of a statement describing the nature, extent, and duration of such instructional activities attached to the form; and

(6) To conduct chemical analysis with controlled substances listed in any schedule, he shall apply on BND Form 225.

(b) If any person is registered and is applying for reregistration:

(1) To manufacture or distribute controlled substances, he shall apply on BND Form 227;

(2) To dispense narcotic or nonnarcotic, or to conduct research with nonnarcotic, or to conduct instructional activities with narcotic or nonnarcotic, controlled substances listed in schedules II through V, he shall apply on BND Form 226;

(3) To conduct research with narcotic controlled substances listed in schedules II through V, he shall apply on BND Form 227;

(4) To continue to conduct research with a controlled substance listed in schedule I under an approved research protocol, he shall apply on BND Form 227;

(5) To continue to conduct instructional activities with controlled substance listed in schedule I under an approved instructional statement, he shall apply as a researcher on BND Form 227; and

(6) To conduct chemical analysis with controlled substances listed in any schedule, he shall apply on BND Form 227.

(c) BND Forms 224 and 225 may be obtained at any regional office of the Bureau or by writing to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. BND Forms 226 and 227 will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his registration; if any registered person does not receive such forms within 45 days before the expiration date of his registration, he must promptly give notice of such fact and request such forms by writing to the Registration Branch of the Bureau at the foregoing address.

(d) Each application for registration to handle any basic class of controlled substance listed in schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in schedule II, or to conduct research with any narcotic controlled substance listed in schedule II, shall include the Bureau Controlled Substances Code Number, as set forth in Part 308 of this chapter, for each basic class or substance to be covered by such registration.

(e) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g., general power of attorney) accompanies the application.

§ 301.33 Application to manufacture a new narcotic controlled substance.

Any application for registration to manufacture a narcotic controlled substance subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) after May 1, 1971, where the manufacturing process involves chemical synthesis (whether from narcotic materials or not) shall be accompanied by an outline of the process of synthesis on BND Form 130, identifying the substances from which the substance is to be made and the substances resulting from each successive stage of the process and indicating in each instance whether the substance is isolated and weighed or measured or remains in solution in a continuing process of manufacture. The applicant need not disclose any technical detail of the process which he regards as a trade secret (including temperature, pressure, volume, and catalyst used to aid the process), but must identify each

substance used in or resulting from successive stages of manufacture in order to notify the Bureau of narcotic precursors and byproducts. BND Form 130 will, if requested by the applicant, be treated as confidential and subject to the protection provided in section 402(a)(8) of the Act (21 U.S.C. 842(a)(8)).

§ 301.34 Filing of application; joint filings.

(a) All applications for registration shall be submitted for filing to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

§ 301.35 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Director may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Director shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 301.36 and has no bearing on whether the application will be granted.

§ 301.36 Additional information.

The Director may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Director in granting or denying the application.

§ 301.37 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Director at any time before the date on which the applicant receives an order to show cause pursuant to § 301.48, or before the date on which a notice of hearing on the application is published pursuant to § 301.43, whichever is sooner. An application may be amended or withdrawn with permission of the Director at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION

§ 301.41 Administrative review generally.

The Director may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to Subpart A of Part 316 of this chapter. The Director shall review the application for registration and other information gathered by the Bureau regarding an applicant in order to determine whether the applicable standards of section 303 of the Act (21 U.S.C. 823) have been met by the applicant.

§ 301.42 Applications for research in schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances in schedule I, the Director shall refer such application to the Secretary, who shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Secretary, in determining the merits of a research protocol, shall consult with the Director as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use. If the Secretary finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, he shall so notify the Director, and the Director shall register the applicant unless he finds registration should be denied on a ground specified in section 304(a) of the Act (21 U.S.C. 824(a)).

(b) If the Secretary is unable to find the applicant qualified or the Director finds that grounds exist for the denial of the application, the Director shall issue an order to show cause pursuant to § 301.48 and, if requested by the applicant, hold a hearing on the application pursuant to § 301.51.

§ 301.43 Application for bulk manufacture of schedule I and II substances.

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in schedule I or II, the Director shall, upon the filing of such application, publish in the FEDERAL REGISTER a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the FEDERAL REGISTER, file with the Director written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application. If a hearing is requested, the Director shall hold a hearing on the application pursuant to § 301.51. Notice of the hearing shall be published in the FEDERAL REGISTER and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be less than 30 days after the date of publication of such notice in the FEDERAL REGISTER. A hearing pursuant to this section may be consolidated with a hearing held pursuant to § 301.44 or § 301.45.

(b) In order to provide adequate competition, the Director shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

(c) This section shall not apply to the manufacture of basic classes of controlled substances listed in schedule I as an incident to research authorized pursuant to § 301.42 or to the manufacture of basic classes of controlled substances listed in schedules I and II under a registration to conduct chemical analysis with controlled substances.

§ 301.44 Certificate of registration; denial of registration.

(a) The Director shall issue a Certificate of Registration (BND Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 303 of the Act (21 U.S.C. 823). In the event that the issuance of registration or reregistration is not required, the Director shall deny the application. Before denying any application, the Director shall issue an order to show cause pursuant to § 301.48 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 301.51.

(b) The Certificate of Registration (BND Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Bureau Controlled Substances Code Number (as set forth in Part 308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration.

The registrant shall prominently display the Certificate of Registration at the registered location.

§ 301.45 Suspension or revocation of registration.

(a) The Director may suspend any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time he determines.

(b) The Director may revoke any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Director shall issue an order to show cause pursuant to § 301.48 and, if requested by the registrant, shall hold a hearing pursuant to § 301.51. Notwithstanding the requirements of this section, however, the Director may suspend any registration pending a final order pursuant to § 301.46.

(d) Upon service of the order of the Director suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration and any order forms in his possession to the nearest office of the Bureau. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant pursuant to Part 303 of this chapter. Also, upon service of the order of the Director revoking registration, the registrant shall, as instructed by the Director.

(1) Deliver all controlled substances in his possession to the nearest office of the Bureau or to authorized agents of the Bureau; or

(2) Place all controlled substances in his possession under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his possession to the nearest office of the Bureau. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to Part 303 of this chapter. Also, the registrant shall, as instructed by the Director.

(1) Deliver to the nearest office of the Bureau or to authorized agents of the Bureau all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Place all of such substances under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

§ 301.46 Suspension of registration pending final order.

(a) The Director may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Director so suspends, he shall serve with the order to show cause pursuant to § 301.48 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration and any order forms in his possession to the nearest office of the Bureau. The suspension of any registration under this section shall suspend any quota fixed for the registrant pursuant to Part 303 of this chapter. Also, upon service of the order of the Director immediately suspending registration, the registrant shall, as instructed by the Director.

(1) Deliver all affected controlled substances in his possession to the nearest office of the Bureau or to authorized agents of the Bureau; or

(2) Place all of such substances under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Director or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to § 301.48, which request shall be granted by the Director, who shall fix a date for such hearing as early as reasonably possible.

§ 301.47 Extension of registration pending final order.

In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Director has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Director so issues his order. The Director may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Director finds that such extension is not inconsistent with the public health and safety.

§ 301.48 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Bureau regarding the applicant, the Director is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Director shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Bureau regarding any registrant, the Director determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Director shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Director at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing pursuant to § 301.55. If a hearing is requested, the Director shall hold a hearing at the time and place stated in the order, pursuant to § 301.51.

(e) When authorized by the Director, any agent of the Bureau may serve the order to show cause.

HEARINGS

§ 301.51 Hearings generally.

(a) In any case where the Director shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823–824), by §§ 301.52–301.57, and by the procedures for administrative hearings under the Act set forth in §§ 316.41–316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

§ 301.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Director shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substance listed in schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 301.53 Waiver or modification of rules.

The Director or the presiding officer (with respect to matters pending before

him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 301.54 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 301.42–301.45 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the FEDERAL REGISTER in the case of § 301.43), file with the Director a written request for a hearing in the form prescribed in § 316.47 of this chapter.

(b) Any person entitled to and desiring to participate in a hearing pursuant to § 301.43 and desiring to do so in the form prescribed in § 316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance, shall, within 30 days of the date of publication of notice of the hearing in the FEDERAL REGISTER, file with the Director a written notice of his intention to participate in such hearing.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §§ 301.42–301.45 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 301.42–301.45 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing, if scheduled, and issue his final order pursuant to § 301.57 without a hearing.

§ 301.55 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to § 301.43 shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any other hearing for the denial of a registration, the Bureau shall have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(c) At any hearing for the revocation or suspension of a registration, the Bureau shall have the burden of proving that the requirements for such revocation or suspension to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

§ 301.56 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless expedited pursuant to § 301.46(c)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 301.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Director, the Director shall issue his order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to manufacture in bulk a basic class of any controlled substance listed in schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Director shall serve one copy of his order upon each party in the hearing.

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§ 301.61 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by filing an application in the same manner as an application for new registration. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

§ 301.62 Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Director promptly of such fact. In the event of a change in name or address, the person may apply for a new Certificate of Registration in advance of the effective date of such change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.

§ 301.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Director may specifically designate and then only pursuant to his written consent.

SECURITY REQUIREMENTS

§ 301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Director shall use the security requirement set forth in §§ 301.72–301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Director after evaluation of the overall security system and needs of the applicant or registrant.

(b) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

(c) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

(d) Physical security controls of persons presently registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 shall be deemed to comply substantially with the standards set forth in §§ 301.72, 301.73, and 301.75: *Provided*, That the Bureau has previously approved them. All such persons shall notify the Bureau before June 1, 1971, indicating that prior Bureau approval was given and either describing the physical security controls or, if such a description has previously been filed with the Bureau, stating that such description has been so filed. Any new facilities or work or storage areas constructed or utilized by such persons for controlled substances, which facilities or work or storage areas have not been previously approved by the Bureau, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 301.72, 301.73, and 301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Bureau.

§ 301.72 [Reserved]

§ 301.73 [Reserved]

§ 301.74 Other security controls for nonpractitioners.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Bureau or with the appropriate State-controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Regional Office of the Bureau in his region of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Regional Office of the Bureau in his region of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The registrant shall also complete BND Form 106 regarding such theft or loss.

(d) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

§ 301.75 Physical security controls for practitioners.

(a) Controlled substances listed in schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in schedules III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

§ 301.76 Other security controls for practitioners.

(a) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, at any time.

(b) The registrant shall notify the Regional Office of the Bureau in his region of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete BND Form 106 regarding such loss or theft.

PART 302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

Sec.

302.01 Scope of Part 302.
302.02 Definitions.
302.03 Symbol required; exceptions.
302.04 Location and size of symbol on label.
302.05 Location and size of symbol on labeling.
302.06 Effective dates of labeling requirements.
302.07 Sealing of controlled substances.

AUTHORITY: The provisions of this Part 302 issued under secs. 301, 305, 501(b), 84 Stat. 1253, 1256, 1271; 21 U.S.C. 821, 825, 871(b).

§ 302.01 Scope of Part 302.

Requirements governing the labeling and packaging of controlled substances pursuant to section 305 of the Act (21 U.S.C. 825) are set forth generally by that section and specifically by the sections of this part.

§ 302.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(b) The term "label" means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(c) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any controlled substance or any of its commercial containers or wrappers, or (2) accompanying such controlled substance.

(d) The term "manufacture" means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term "manufacturer" means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(e) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or § 301.02 of this chapter.

§ 302.03 Symbol required; exceptions.

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Director pursuant to § 303.31 of this chapter) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	*Symbol*
Schedule I	Ⓘ or C–I.
Schedule II	Ⓘⓘ or C–II.
Schedule III	Ⓘⓘⓘ or C–III.
Schedule IV	Ⓘⓥ or C–IV.
Schedule V	Ⓥ or C–V.

The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

(g) The symbol is not required on a commercial container containing, or on the labelling of, a controlled substance intended for export from the United States.

§ 302.04 Location and size of symbol on label.

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in schedules I through V. The symbol must be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

§ 302.05 Location and size of symbol on labeling.

The symbol shall be prominently located on all labeling other than labels covered by § 302.04. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

§ 302.06 Effective dates of labeling requirements.

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on May 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 302.03.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on May 1, 1971, and thereafter transferred to another schedule or is added to any schedule after May 1, 1971, and which is packaged more than 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of § 302.03.

(c) The Director may, in the case of any controlled substance, require compliance with the requirements of § 302.03 within a period of time shorter than required by this section if he finds that public health or safety necessitate an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

§ 302.07 Sealing of controlled substances.

(a) On each bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedules I and/or II, and of any narcotic controlled substance listed in schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use under Federal law prior to May 1, 1971, shall be deemed acceptable for use under this section.

PART 303—QUOTAS

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AUTHORITY: The provisions of this Part 303 issued under secs. 301, 306, 501(b), 84 Stat. 1253, 1257, 1258, 1271; 21 U.S.C. 821, 826, 871(b).

GENERAL INFORMATION

§ 303.01 Scope of Part 303.

Procedures governing the establishment of production and manufacturing quotas on basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 826) are governed generally by that section and specifically by the sections of this part.

§ 303.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "hearing" means any hearing held pursuant to this part regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quotas.

(b) The term "inventory" means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

(c) The term "net disposal" means the quantity of a basic class of controlled substance sold, exchanged, given away, used in the production of another substance (whether a controlled substance or not), contained in or combined with other substances, or otherwise consumed by or transferred to another person by the registrant during a stated period, less the quantity returned to the registrant by any purchaser and the quantity sold or transferred by the registrant to another registered manufacturer of the same basic class of controlled substance.

(d) The term "registrant" means any person registered pursuant to section 303 of the Act (21 U.S.C. 823).

(e) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and § 301.02 of this chapter.

AGGREGATE PRODUCTION AND PROCUREMENT QUOTAS

§ 303.11 Aggregate production quotas.

(a) The Director shall, on or before May 1 of each year, determine the total quantity of each basic class of controlled substance listed in schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

(b) In making his determinations, the Director shall consider the following factors:

(1) Total net disposal of the class by all manufacturers during the current and 2 preceding years;

(2) Trends in the national rate of net disposal of the class;

(3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;

(4) Projected demand for such class as indicated by procurement quotas requested pursuant to § 303.12; and

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Director finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Director shall, on or before May 1 of each year, publish in the FEDERAL REGISTER general notice of an aggregate production quota for any basic class determined by him under this section. A copy of notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class. Any interested person may, within 30 days from the date of publication of the notice, request a hearing on the aggregate production quota by filing with the Director a written request for a hearing in the form prescribed in § 316 of this chapter. If a hearing is requested and reasonable grounds are shown, the Director shall hold a public hearing on the aggregate production quota for the basic class. Notice of the hearing shall be published in the FEDERAL REGISTER at least 30 days prior to the hearing and mailed simultaneously to all persons to whom the notice of the determination of the aggregate production quota was mailed.

§ 303.12 **Procurement quotas.**

(a) In order to determine the estimated needs for, and to insure an adequate and uninterrupted supply of, basic classes of controlled substances listed in schedules I and II (except raw opium) the Director shall issue procurement quotas authorizing persons to procure and use quantities of each basic class of such substances for the purpose of manufacturing such class into dosage forms or into other substances.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in schedule I or II (except raw opium) for purposes of manufacturing, shall apply on BND Form 194 for a procurement quota for such basic class. A separate application must be made for each basic class desired to be procured or used. The applicant shall state whether he intends to manufacture the basic class himself or purchase it from another manufacturer. The applicant shall state separately each purpose for which the basic class is desired, the quantity desired for that purpose during the next calendar year, and the quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years. If the purpose is to manufacture the basic class into dosage form, the applicant shall state the official name, common or usual name, chemical name, or brand name of that form. If the purpose is to manufacture another substance, the applicant shall state the official name, common or usual name, chemical name, or brand name of the substance, and, if a controlled substance listed in any schedule, the schedule number and Bureau Controlled Substances Code Number, as set forth in Part 308 of this chapter, of the substance. If the purpose is to manufacture another basic class of controlled substance listed in schedule I or II, the applicant shall also state the quantity of the other basic class which the applicant has applied to manufacture pursuant to § 303.22 and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class. BND Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of BND Form 250 may be obtained from, and shall be filed with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(c) The Director shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

(1) All quantities of such class necessary to manufacture all quantities of other basic classes of controlled substances listed in schedules I and II which the applicant is authorized to manufacture pursuant to § 303.23; and

(2) Such other quantities of such class as the applicant has applied to procure and use and are consistent with his past use, his estimated needs, and the total quantity of such class that will be produced.

(d) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Director with a statement showing the need for the adjustment. The Director shall increase or decrease the procurement quota of such person as and to the extent that he finds, after considering the factors enumerated in paragraph (c) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(e) The following persons need not obtain a procurement quota:

(1) Any person who is registered to manufacture a basic class of controlled substance listed in schedule I or II and who uses all of the quantity he manufactures in the manufacture of a substance not controlled under the Act;

(2) Any person who is registered to conduct chemical analysis with controlled substances; and

(3) Any person who is registered to conduct research with a basic class of controlled substance listed in schedule I and who is authorized to manufacture a quantity of such class pursuant to § 301.22(b)(3) of this chapter.

INDIVIDUAL MANUFACTURING QUOTAS

§ 303.21 **Individual manufacturing quotas.**

(a) The Director shall, on or before July 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in schedule I or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. Any manufacturing quota fixed and issued by the Director shall be subject to his authority to reduce or limit it at a later date pursuant to § 303.26 and to his authority to revoke or suspend it at any time pursuant to §§ 301.45 and 301.46 of this chapter.

(b) No individual manufacturing quota shall be required for registrants listed in § 303.12(e).

§ 303.22 **Procedure for applying for manufacturing quotas.**

Any person who is registered to manufacture any basic class of controlled substance listed in schedule I or II and who desires to manufacture a quantity of such class shall apply on BND Form 189 for a manufacturing quota for such quantity of such class. Copies of BND Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. A separate application must be made for each basic class desired to be manufactured. The applicant shall state:

(a) The name and Bureau Controlled Substances Code Number as set forth in Part 308 of this chapter, of the basic class.

(b) For the basic class in each of the current and preceding 2 calendar years,

(1) The authorized manufacturing quota, if any;

(2) The actual or estimated net disposal;

(3) The actual or estimated inventory allowance pursuant to § 303.24; and

(4) The actual or estimated inventory as of December 31;

(c) For the basic class in the next calendar year,

(1) The desired manufacturing quota; and

(2) Any additional factors which the applicant finds relevant to the fixing of his manufacturing quota, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

§ 303.23 **Procedure for fixing individual manufacturing quotas.**

(a) In fixing individual manufacturing quotas for a basic class of controlled substance listed in schedule I or II, the Director shall allocate to each applicant who is currently manufacturing such class a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted (1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to § 303.24, and (2) By any other factors which the Director deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a basic class of controlled substance listed in schedule I or II, the Director shall allocate to each applicant who is not currently manufacturing such class a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the next calendar year, as determined by the Director, adjusted (1) By the amount necessary to

provide the applicant his estimated inventory allowance for the next calendar year, pursuant to § 303.24, and (2) By any other factors which the Director deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) the national rate of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Director shall, on or before January 31 of each year, adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to § 303.24.

§ 303.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 303.23, each registered manufacturer shall be allowed as a part of such quota an amount sufficient to maintain an inventory equal to,

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Director.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 65 percent of his estimated net disposal of that class for that year, as determined at the time his quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 percent of his estimated net disposal, his quota for that class is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. The Director may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of his estimated net disposal, upon such conditions and within such limitations as the Director may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to him under a manufacturing quota, and his inventory of that class is less than 40 percent of his estimated net disposal of that class for that year, the Director may, upon application pursuant to § 303.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

§ 303.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a basic class of controlled substance listed in schedule I or II may file with the Director an application on Bureau Form 189 for an increase in such quota in order for him to meet his estimated net disposal, inventory and other requirements during the remainder of such calendar year.

(b) The Director, in passing upon a registrant's application for an increase in his individual manufacturing quota shall take into consideration any occurrences since the filing of such registrant's initial quota application that may require an increased manufacturing rate by such registrant during the balance of the calendar year. In passing upon such application the Director may also take into consideration the amount, if any, by which his determination of the total quantity for the basic class of controlled substance to be manufactured under § 303.11 exceeds the aggregate of all the individual manufacturing quotas for the basic class of controlled substance, and the equitable distribution of such excess among other registrants.

§ 303.26 Reduction in individual manufacturing quotas.

The Director may at any time reduce an individual manufacturing quota for a basic class of controlled substance listed in schedule I or II which he has previously fixed in order to prevent the aggregate of the individual manufacturing quotas outstanding or to be granted from exceeding the aggregate production quota which has been established for that class pursuant to § 303.11. If a quota assigned to a new manufacturer pursuant to § 303.23(b), or if a quota assigned to any manufacturer is increased pursuant to § 303.24(c), or if an import permit issued to an importer pursuant to Part 312 of this chapter, causes the total quantity of a basic class to be manufactured and imported during the year to exceed the aggregate production quota which has been established for that class pursuant to § 303.11, the Director may proportionately reduce the individual manufacturing quotas of all other registrants to keep the aggregate production quota within the limits originally established, or, alternatively, the Director may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 303.24(b) or § 301.45 or § 301.46 of this chapter, or is abandoned pursuant to § 303.27.

§ 303.27 Abandonment of quota.

Any manufacturing assigned an individual manufacturing quota for any basic class pursuant to § 303.23 may at any time abandon his right to manufacture all or any part of such quota by filing with the Distribution Audit Branch a written notice of such abandonment, stating the Bureau Controlled Substances Code Number, as set forth in Part 308 of this chapter, of the substance and the amount which he has chosen not to manufacture. The Director may, in his discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

HEARINGS

§ 303.31 Hearings generally.

(a) In any case where the Director shall hold a hearing regarding the determination of an aggregate production quota pursuant to § 303.11(c), the procedures for such hearing shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 303.32–303.37, and by the procedures for administrative hearings under the Act set forth in §§ 316.41–316.67 of this chapter.

(b) In any case where the Director shall hold a hearing regarding the issuance, adjustment, suspension, or denial of a procurement quota pursuant to § 303.12, or the issuance, adjustment, suspension, or denial of an individual manufacturing quota pursuant to §§ 303.21–303.27, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedures Act (5 U.S.C. 551–559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 303.32–303.37, and by the procedures for administrative hearings under the Act set forth in §§ 316.41–316.67 of this chapter.

§ 303.32 Purpose of hearing.

(a) If requested by an interested person who shows reasonable grounds therefor, the Director shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the determination of any aggregate production quota.

(b) If requested by a person applying for or holding a procurement quota or an individual manufacturing quota, the Director shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of such quota to such person, but the Director need not hold a hearing on the suspension of a quota pursuant to § 301.45 or § 301.46 of this chapter separate from a hearing on the suspension of registration pursuant to those sections.

(c) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 303.33 Waiver or modification of rules.

The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or

waiver shall be made a part of the record of the hearing.

§ 303.34 Request for hearing or appearance; waiver.

(a) Any applicant or registrant who desires a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota shall, within 30 days after the date of receipt of the issuance, adjustment, suspension, or denial of such quota, file with the Director a written request for a hearing in the form prescribed in § 316.47 of this chapter.

(b) Any interested person who desires to participate in a hearing on the determination of an aggregate production quota, which hearing is requested pursuant to § 303.11(c), shall, within 30 days of the date of publication of notice of the hearing in the FEDERAL REGISTER, file with the Director a written notice of his intention to participate in such hearing in the form prescribed in § 316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to § 303.11(c), may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to § 303.11(c), fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing, if scheduled, and issue his final order pursuant to § 303.37 without a hearing.

§ 303.35 Burden of proof.

(a) At any hearing regarding the determination of an aggregate production quota, each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement or individual manufacturing quota, the Bureau shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

§ 303.36 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to § 303.34, the Director shall hold such hearing. Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Director shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to § 303.11(c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 303.37 Final order.

As soon as practicable after the presiding officer has certified the record to the Director, the Director shall issue his order on the determination of the aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as the case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Director shall serve one copy of his order upon each party in the hearing.

TRANSITIONAL REGULATIONS

§ 303.41 Quota system for 1971.

For purposes of fixing aggregate production and individual manufacturing quotas for basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 326) for the calendar year 1971 only, procedures for fixing quotas on narcotic drugs prescribed in regulations in effect prior to the effective date of this part (i.e., §§ 307.121–307.126 of this chapter) shall be utilized.

§ 303.42 Quota system for 1972.

For purposes of fixing aggregate production and individual manufacturing quotas for basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 326) for the calendar year 1972 only, applications required pursuant to §§ 303.12 (b) and 303.22 shall be filed no later than September 1, 1971.

PART 304—RECORDS AND REPORTS OF REGISTRANTS

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AUTHORITY: The provisions of this Part 304 issued under secs. 301, 304, 501(b), 1008(d), 1015, 84 Stat. 1253, 1258, 1259, 1271, 1289, 1291; U.S.C. 821, 824, 871(b), 958(d), 965.

GENERAL INFORMATION

§ 304.01 Scope of Part 304.

Inventory and other records and reports required under section 307 or section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those sections and by the sections of this Part.

§ 304.02 Definitions.

As used in this Part, the following terms shall have the meaning specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert of other material kept with or within a commercial container, nor any carton, crate, drug, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(c) The term "dispenser" means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(d) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(e) The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(f) The term "name" means the official name, common or usual name, chemical name, or brand name of a substance.

(g) The term "pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

(h) The term "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(i) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in §§ 301.02 and 311.02 of this chapter.

§ 304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.

(b) A registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in schedules II through V which he prescribes or administers in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he dispenses other than by prescribing or administering.

(c) A registered individual practitioner is not required to keep records with respect to nonnarcotic controlled substances listed in schedules II through V which he dispenses in any manner unless he regularly charges his patients, either separately or together with charges for other professional services, for such substances so dispensed (e.g., when he substitutes his services for those of a pharmacist).

(d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Bureau of the name, address, and registration number of the establishment maintaining such records.

(e) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Bureau of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by paragraphs (d) and (e) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

§ 304.04 Maintenance of records and inventories.

(a) Every inventory and other record required to be kept under the Part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or record, for inspecting and copying by authorized employees of the Bureau, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to § 305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant obtains from the Bureau approved of his central recordkeeping system and a permit to keep central records. The central recordkeeping system of any person whose system was approved by the Bureau prior to May 1, 1971, shall continue to be approved under this paragraph if such person satisfies the Bureau by July 1, 1971, of such approval and applies for a permit to keep central records. The permit to keep central records shall be issued by the Bureau to a registrant upon application if the Bureau approves his central recordkeeping system and shall be subject to the following conditions:

(1) The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;

(2) The registrant agrees to deliver all or any part of such records to the registered location within 48 hours of receipt of a written request from the Bureau for such records and, if the Bureau chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Bureau to inspect such records at the central location upon request by such employees without a warrant of any kind; and

(3) The failure of the registrant to perform his agreements under the permit shall revoke without further action by the Bureau such permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under this subparagraph, the registrant shall, within 30 days after such revocation, comply with the requirements of this section that all records be kept at the registered location.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(c) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (b) of this section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

INVENTORY REQUIREMENTS

§ 304.11 General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and

substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 304.18.

(d) A registrant may take an inventory on a date that is within 4 days of his biennial inventory date pursuant to § 304.13 if he notifies in advance the Regional Director of the Bureau in his region of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

§ 304.12 Initial inventory date.

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with §§ 304.15–304.18, as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with §§ 304.15–304.18, as applicable.

§ 304.13 Biennial inventory date.

Every 2 years following the date on which the initial inventory is taken by a registrant pursuant to § 304.12, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken (a) on the day of the year on which the initial inventory was taken or (b) on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply or (c) on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Bureau of this election and of the date on which the biennial inventory will be taken.

§ 304.14 Inventory date for newly controlled substances.

On the effective date of a rule by the Director pursuant to §§ 308.48, 308.49, or 308.50 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to § 304.13.

§ 304.15 Inventories of manufacturers.

Each registered manufacturer shall include the following information in his inventory:

(a) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form:

(1) The name of the substance; and

(2) The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

(b) For each controlled substance in the process of manufacture on the inventory date:

(1) The name of the substance;

(2) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;

(3) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof; and

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(3) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(4) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(5) The total quantity of the substance in all forms to the nearest metric unit weight.

(d) For each controlled substance not included in paragraphs (a), (b) or (c) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

(1) The name of the substance;

(2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(3) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

§ 304.16 Inventories of distributors.

Each registered distributor shall include in his inventory the same information required of manufacturers pursuant to § 304.15 (c) and (d).

§ 304.17 Inventories of dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to § 304.03 shall include in his inventory the same information required of manufacturers pursuant to § 304.15 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in schedule I or II, he shall make an exact count or measure of the contents; and

(b) If the substance is listed in schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

§ 304.18 Inventories of importers and exporters.

Each registered importer or exporter shall include in his inventory the same information required of manufacturers pursuant to § 304.15 (a), (c), and (d). Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

§ 304.19 Inventories for chemical analysts.

Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to § 305.15 (a), (c), and (d) as to substances which have been manufactured, imported, or received by the laboratory conducting the inventory. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance

need not be included in the inventory. Laboratories of the Bureau may possess up to 150 grams of any hallucinogenic substance in schedule I without regard to a need for an inventory of those substances.

CONTINUING RECORDS

§ 304.21 General requirements for continuing records.

(a) On and after May 1, 1971, every registrant required to keep records pursuant to § 304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 304.04(a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in § 304.25.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

§ 304.22 Records of manufacturers.

Each registered manufacturer shall maintain records with the following information:

(a) For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity, and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

(i) The date and batch or other identifying number of each manufacture;

(ii) The quantity used in the manufacture;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(iv) The number of units of finished form manufactured;

(v) The quantity used in quality control;

(vi) The quantity lost during manufacturing and the causes therefor, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(6) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subparagraph (5) of this paragraph;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed.

(b) For each controlled substance in finished form,

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subparagraph (5) of paragraph (a) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers in each importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each manufacture;

(ii) The operation performed (e.g., repackaging or relabeling);

(iii) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefor, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(7) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

§ 304.23 Records for distributors.

Each registered distributor shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(d) The number of commercial containers of each such finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;

(e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address, and registration number of the person to whom the containers were distributed;

(f) The number of commercial containers of such finished form exported directly by the registrant (under a registration as an exporter), including the

date of and the number of containers in each exportation; and

(g) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

§ 304.24 Records for dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to § 304.03 shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and

(e) The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

§ 304.25 Records for importers.

Each registered importer shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;

(c) The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and

(d) The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to § 304.22 (a)(4) or (b)(5)), including the date and manner of disposal and the quantity disposed.

§ 304.26 Records of exporters.

Each registered exporter shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;

(c) The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to § 304.22 (a)(8) or (b)(8); and

(d) The quantity disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity disposed.

§ 304.27 Records for chemical analysis.

(a) Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;

(4) The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Order forms, import and export permits, import invoices, and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

(c) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(d) Records relating to known or suspected controlled substances received as samples for analysis are not required under paragraph (a) of this section.

REPORTS

§ 304.31 Reports from manufacturers and importers.

(a) Each registered manufacturer and registered importer shall submit a quarterly report (BND Form 234) accounting for all stocks of narcotic controlled substances on hand at the beginning and at the end of the quarter, and for all receipts (BND Form 234a), dispositions (BND Form 234b), manufacturing (BND Form 234c) and packaging (BND Form 234d), of such substances. The returns shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month succeeding the period for which it is submitted.

(b) All narcotic controlled substances received by a manufacturer or importer, shall be recorded on Form 234a in order and at the time of receipt. Where record on Form 234a cannot, for any good and sufficient reason, be made immediately, the manufacturer or importer shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances by a manufacturer or importer, including exports, distributions, and losses, shall be reported on BND Form 234b. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet separate entries shall be used to report dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained. The details of all exports and all domestic distributions of narcotic controlled substances shall be reported in full on BND Form 234b, except that the details of distributions of narcotic controlled substances listed in schedules III, IV, and V sold to practitioners shall be included in summarized entries on BND Form 234b. For all such distributions not reported in detail the manufacturer shall have available for inspection original sales orders, delivery slips, or other papers or records sufficient to fully evidence and explain the dispositions.

(d) All narcotic controlled substances used in the production of other drugs or preparations, with the exception of transactions involving original manufacture from raw opium or coca leaves, shall be entered on BND Form 234c in the order and at the time they are placed into the process of manufacture. All narcotic controlled substances and preparations produced therefrom shall be entered on the same form, at the time of production, which entry shall be clearly identified with the entry of substances used in their production. Where record of "Used for Production" or "Production"

cannot be made immediately the manufacturer shall have available such batch tags, production orders, or other papers as may be required to evidence any unrecorded quantity used or produced. Any loss in manufacture, and any recoverable wastes salvaged from the manufacture shall be reported. All such wastes shall be returned to raw stock and included in the report of raw materials on hand at the end of the month. Any narcotic controlled substances actively in process of manufacture at the end of the month shall be so reported. Where substances are placed in process during one quarter and a portion of the production is removed from process as finished goods during the same quarter, the portion thus removed from process shall be reported "Produced" and the remainder reported as "In process" at the close of the period. Narcotic controlled substances placed in process for the manufacture of narcotic controlled substances listed in schedule V shall be reported on a separate BND Form 234c, on which the kind and quantity of narcotic used and the name of the substance to be produced therefrom shall be stated.

(e) All narcotic controlled substances, either bulk finished goods or goods already packaged, which are used during the quarter for packaging or repackaging into commercial containers shall be reported as credit entries in BND Form 234d, and in each instance clearly identified with the entry of substance used in such packaging. A separate entry shall be made for each different size of commercial container produced, but all entries representing a single packaging lot shall be grouped together. The number of commercial containers of a given size produced, the size of the commercial container (indicating the number of pills, tablets, ounces, etc.), the narcotic controlled substance contained in each unit in the commercial container, the total narcotic controlled substance content of each commercial container, and the aggregate narcotic controlled substance content of all commercial containers, represented by the entry shall be indicated. The recoverable wastes salvaged from the packaging operation and the losses in packaging shall be shown as credit entries on the form. All recoverable wastes reported during the quarter shall be returned to raw stock and further accounted for as raw materials. Any goods actively in process of packaging at the close of the quarter shall be so reported. Where substances are placed in process for packaging during one quarter and a portion thereof are removed as commercial containers, produced during the same quarter, the portion thus removed shall be reported as commercial containers produced and the remainder reported as in process at the end of the quarter.

(f) Each manufacturer and importer shall submit as a part of his fourth quarterly report (BND Form 234) an inventory (BND Form 234e) of narcotic controlled substances which are in his possession on December 31 of each year. The substances shall be classified as follows:

(1) Raw materials.
(2) Goods in process.
(3) Finished bulk stock.
(4) Finished goods in marketable commercial containers.
(5) Miscellaneous stock.

§ 304.32 Reports of distributors and exporters.

(a) Every registered distributor and registered exporter shall submit a monthly report on BND Form 235 and its supplements 235a and 235b accounting for all transactions involving narcotic controlled substances listed in schedules I and II, including all receipts (BND Form 235a) and dispositions (BND Form 234b). The report shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month succeeding that for which the return is submitted.

(b) All narcotic controlled substances received by a distributor or exporter listed in schedules I and II shall be recorded on BND Form 235a in order and at the time of receipt. Where a record on BND Form 235a cannot, for any good and sufficient reason, be made immediately, the distributor or exporter shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or other receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I and II, including distributions, exports, and losses, shall be reported on BND Form 235b. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet separate entries shall be made of dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

(d) Each distributor and exporter shall submit, as part of his fourth quarterly report on BND Form 235 and its supplements, an inventory on BND Form 235c of narcotic controlled substances listed in schedules I and II which are in his possession on December 31 of each year. A separate entry shall be made for each narcotic substance as follows:

(1) The name, quantity, and narcotic content of the drug or preparation;

(2) The size of each commercial container; and

(3) The number of commercial containers.

(e) The distributor shall report on BND Form 235 a complete summary of transactions for the month.

§ 304.33 Reports from manufacturers importing opium.

(a) Every manufacturer importing crude opium shall submit, in addition to the report on BND Form 234 and its supplements, BND Form 247 and its supplements, 247a and 247b, accounting for the importation and for all manufacturing operations performed between importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in the quarterly returns on BND Form 234 and its supplements. BND Form 247 and its supplements shall be submitted quarterly to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from crude opium shall consist of summaries (BND Forms 247 and 247a) with supporting detail sheets (on BND Form 247b) accounting for original manufacture from crude opium, production from morphine for further manufacture and production from manufacturing opium, and also accounting for stocks of crude opium, manufacturing opium, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (BND Form 247b) supporting the summary of original manufacture from crude opium shall show separately the crude opium used for the manufacture of opium tinctures and extracts, crude opium used for the extraction of alkaloids, crude opium used for the manufacture of controlled substances listed in schedule V, and crude opium used for the production of manufacturing opium; and shall show separately the medicinal opium, alkaloids and salts, opium tinctures and extracts, controlled substances listed in schedule V, and manufacturing opium produced.

(d) Importation of opium shall be reported in summarized entries in the debit summary of the quarterly report (BND Form 234) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (BND Form 234) as transferred to importing manufacturer's report. Such importations shall further be reported in summary (BND Form 247) and supporting detail sheets (BND Form 247b). Products manufactured therefrom shall be reported as produced in accordance with paragraphs (b) and (c) of this section and, with the exception of manufacturing opium, morphine for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (BND Form 234) when reported produced.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. These assays shall be accounted for in terms of its anhydrous morphine alkaloid content. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject

to adjustment, and the necessary adjusting entires shall be made on the next report.

(f) Upon withdrawal of crude opium from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the opium will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(h) Opium products and derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Medicinal opium, morphine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Medicinal opium, tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) Subject to § 303.24(c) of this chapter, no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(j) In making conversions of opium alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multipled by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

§ 304.34 Reports of manufacturers importing medicinal coca leaves.

(a) Every manufacturer importing raw coca leaves for the manufacture of medicinal products shall submit, in addition to the report on BND Form 234 and its supplements, BND Form 168 and its supplements, 168a and 168b, accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopeia, National Formulary, or other recognized standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in quarterly reports on BND Form 234 and its supplements. Reports on Form 168 and its supplements shall be submitted quarterly to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from medicinal coca leaves shall consist of summaries (BND Forms 168 and 168a) with supporting detail sheets (BND Form 168b) accounting for original manufacture from such leaves, conversions or production from manufacturing coca extracts, and also accounting for stocks of raw coca leaves, manufacturing coca extracts, and other crude coca alkaloids.

(c) The detail sheets (BND Form 168b) supporting the summary of original manufacture from medicinal coca leaves, shall show separately the coca leaves used for the manufacture of manufacturing coca extracts, coca leaves used for the direct manufacture of marketable coca tinctures and extracts, and coca leaves used for the extraction of alkaloids, and shall show separately the coca alkaloids and salts, coca tinctures and extracts, and manufacturing coca extracts produced.

(d) Importations of medicinal coca leaves shall be reported in summarized entries in the debit summary of the quarterly report (BND Form 234) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (BND Form 234) as transferred to importing manufacturer's report. Such importations shall further be reported in summary (BND Form 168) and supporting detail sheets (BND Form 168b). Products manufactured therefrom shall be reported as produced in accordance with paragraph (h) of this section and, with the exception of manufacturing coca extracts, residues or bases for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (BND Form 234) when reported produced.

(e) Upon importation of medicinal coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submitting the report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Upon withdrawal of medicinal coca leaves from customs custody, the importing manufacturer shall assign to each bale or container an identification mark or number by which the coca leaves will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(h) Manufacturing coca extracts shall be reported as produced when they come into existence in that form in which they are intended for exclusive use in further manufacture. Cocaine and its salts, ecgonine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product is ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture shall be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) No accumulations of cocaine or ecgonine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks and reported as produced.

(j) In making conversions of coca alkaloids and their salts to cocaine alkaloid and to anhydrous ecgonine alkaloid, the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multipled by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the molecular weight of such alkaloid or salt and the molecular weight of cocaine alkaloid (303.172) or anhydrous ecgonine alkaloid (185.125), as the case may be, such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopeia.

§ 304.35 Reports from manufacturers importing special coca leaves.

(a) Every manufacturer using special coca leaves imported into the United States shall submit a quarterly report (BND Form 249) accounting for all transactions involving such leaves or

substances derived therefrom which contain cocaine or ecgonine, or any salts, derivatives, or preparations from which cocaine or ecgonine may be synthesized or made. This report shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month following the period for which the report is made. Such report shall include a report of all importations of special coca leaves (BND Form 249a), a report of all materials entered into the processes of manufacture (BND Form 249b), a report of the various substances produced therefrom (BND Forms 249c, 249d, and 249e), a report of all such substances destroyed (BND Form 249f), and a summary of operations (BND Form 249g).

(b) The report of importations shall provide in appropriate columns the following data as to each importation:

(1) The date of the import permit;

(2) The serial number of the import permit;

(3) The name of the foreign consignor;

(4) The address of the foreign consignor;

(5) The foreign port of export;

(6) The number of bales imported;

(7) The serial numbers of the bales imported; and

(8) The quantity imported in avoirdupois pounds.

(c) The report of materials entered into the process of manufacture shall provide in appropriate columns the following information as to each lot of leaves dumped:

(1) The lot number of specification, a specification to be assigned to each dump for identification purposes in order to avoid repeating the serial numbers of the bales when the lot is subsequently referred to;

(2) The date the leaves entered into the process of manufacture;

(3) The number of bales dumped;

(4) The serial numbers of the bales;

(5) The quantity of leaves entered into the process of manufacture, stated in avoirdupois pounds;

(6) The quantity of alcohol used for each extraction or wash of the leaves;

(7) The quantity of water used for each water extraction or dilution;

(8) The quantity of any other or additional substance introduced at any stage into the process of manufacture; and

(9) The dry weight of any filter cloth or other absorbent material to be later removed from the process after saturation.

(d) The reports of substances produced from special coca leaves shall provide in columns the following information as to each production lot or dump:

(1) The lot number;

(2) The quantity of ground leaves entered into process, in terms of avoirdupois ounces and the quantity, in ounces and grains, of alkaloid contained therein as determined by analysis;

(3) The quantity of substance in process after each distinct step in the manufacturing process and the total alkaloid contained in each, stated in ounces and grains;

(4) The quantity of exhausted or spent leaves and the quantity of each residue removed from process, and the total alkaloid contained in each, stated in ounces and grains;

(5) The weight of the used filter cloth or other absorbent material removed, after saturation; and

(6) The quantity, in gallons, of finished extract produced.

(e) The report of substances destroyed, shall provide in appropriate columns the following data as to each lot destroyed:

(1) The lot number;

(2) The quantity of spent leaves, residues, and saturated materials destroyed, stated separately for each; and

(3) The name of the Government officer witnessing the destruction.

(f) The summary shall include a complete accounting for all transactions in raw leaves, leaves in process, and residues removed from production processes.

(1) The summary of raw coca leaves shall include:

(i) The quantity of special coca leaves on hand at the beginning of the quarter;

(ii) The quantity of special coca leaves imported during the quarter;

(iii) The quantity of special coca leaves entered into the process of manufacture during the quarter;

(iv) The quantity of special coca leaves on hand at the end of the quarter; and

(v) Any other transaction during the quarter which increased or decreased the quantity of raw coca leaves on hand.

(2) The summary of coca leaves in process shall include:

(i) The quantity of special coca leaves in process at the beginning of the quarter;

(ii) The quantity of such leaves placed in the process during the quarter;

(iii) The quantity of such leaves represented by lots completed during the quarter;

(iv) The quantity of such leaves represented by lots in process at the end of the quarter; and

(v) Any other transaction during the quarter which increased or decreased the quantity of leaves in process.

(3) The summary of residues removed from production processes shall provide in appropriate columns, separately as to spent leaves, each residue and saturated material, the following information:

(i) The quantity of each, on hand at the beginning of the quarter, awaiting destruction;

(ii) The quantity of each removed from process during the quarter;

(iii) The quantity of each destroyed during the quarter;

(iv) The quantity of each on hand at the end of the quarter; and

(v) Any other transaction during the quarter affecting the quantity of such residues on hand.

PART 305—ORDER FORMS

Sec.

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AUTHORITY: The provisions of this Part 305 issued under secs. 301, 308, 501(b), 84 Stat. 1253, 1259, 1260, 1271; 21 U.S.C. 821, 828, 871(b).

§ 305.01 Scope of Part 305.

Procedures governing the issuance, use, and preservation of order forms pursuant to section 308 of the Act (21 U.S.C. 828) are set forth generally by that section and specifically by the sections of this part.

§ 305.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "purchaser" means any registered person entitled to obtain and execute order forms pursuant to § 305.04 and § 305.06.

(c) The term "supplier" means any registered person entitled to fill order forms pursuant to § 305.08.

(d) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and §§ 301.02 and 302.02 of this chapter.

§ 305.03 Distributions requiring order forms.

An order form (BND Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

(a) The exportation of such substances from the United States in conformity with the Act;

(b) The delivery of such substances to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business (but excluding such carriage or storage by the owner of the substance in connection with the distribution to a third person);

(c) The procurement of a sample of such substances by an exempt law enforcement official pursuant to § 316.04(d) of this chapter, provided that the receipt required by that section is used and is preserved in the manner prescribed in this part for order forms;

(d) The procurement of such substances by a civil defense or disaster relief organization, pursuant to § 301.27 of this chapter, provided that the Civil Defense Emergency Order Form required by that section is used and is preserved with other records of the registrant; and

(e) The purchase of such substances by the master of a vessel pursuant to § 301.28(a)(3) of this chapter: *Provided,* That the special order form provided by the U.S. Public Health Service as required by that section is used and preserved in the manner prescribed on this order form.

§ 305.04 Persons entitled to obtain and execute order forms.

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in schedules I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his registration as to the substances being purchased has not expired or been revoked or suspended.

§ 305.05 Procedure for obtaining order forms.

(a) Order forms are issued in books of six forms, each form containing an original, duplicate and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit of three books of forms will be furnished on any requisition, unless additional books are specifically requested and a reasonable need for such additional books is shown.

(b) Any person applying for a registration which would entitle him to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him to obtain order forms may requisition such forms for the first time on BND Form 222d, which may be obtained from the Registration Branch of the Bureau. Any person already holding order forms may requisition additional forms only on BND Form 222b, which is contained in each book of order forms. All requisitions shall be submitted to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to § 305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant and the Bureau Controlled Substances Code Number (set forth in Part 308 of this chapter) of the basic class of controlled substance listed in schedule I which the registrant is authorized to handle, if any, printed thereon. In the case of order forms issued to a person registered to conduct chemical analysis with controlled substances listed in schedule I, the order forms shall not be confined to a single such substance and may be used to purchase any of such substances. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Branch of the Bureau by returning the forms with notification of the error.

§ 305.06 Procedure for executing order forms.

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the BND Form 222c. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. There are five lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. The total number of items ordered shall be noted on that form in the space provided. Attachment of extra sheets to an order form, or use of order forms for substances other than controlled substances listed in schedules I and II, is not permitted.

(c) An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item the form shall show the name of the article ordered, the finished or bulk form of the article (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter or V.S.P.), the number of units or volume in each commercial or bulk container (e.g., 100-tablet bottle or 3-milliliter vial) or the quantity or volume of each bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the article if not in pure form. The catalogue number of the article may be included at the discretion of the purchaser.

(d) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any one form.

(e) Each order form shall be signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to § 305.05(c). The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

§ 305.07 Power of attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his behalf by filing a power of attorney on BND Form 231 for each such individual with the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and shall contain the signature of the individual being authorized to obtain and execute order forms, which individual shall affirm his signature. Any power of attorney may be revoked at any time by filing a notice of revocation, signed by the person who signed the power of attorney, with the Registration Branch at the foregoing address. It shall be necessary to submit a new power of attorney upon the reregistration of a purchaser only if the application for reregistration was signed by a person different from the person who signed the existing power of attorney.

§ 305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in schedules I or II under section 303 of the Act (21 U.S.C. 823) or an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration, may dispose of any controlled substances listed in schedule I or II in his possession pursuant to order forms;

(b) A person who has obtained any controlled substance in schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance pursuant to the order form of the latter person; and

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, § 307.11 of this chapter.

§ 305.09 Procedure for filling order forms.

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the

supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Bureau on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his own files and forward Copy 2 to the Regional Director of the Bureau in the region in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 305.10 Procedure for endorsing order forms.

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 305.09 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of Copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he desires to do so, in accordance with § 305.09 (b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

§ 305.11 Unaccepted and defective order forms.

(a) No order form shall be filled if it:

(1) Is not complete, legible, or properly prepared, executed or endorsed; or

(2) Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with § 305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

§ 305.12 Lost and stolen order forms.

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Registration Branch of the Bureau shall immediately be notified.

§ 305.13 Preservation of order forms.

(a) The purchaser shall retain Copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain Copy 1 of each order form which he has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to § 305.06(e)) at the registered location printed on the order form.

§ 305.14 Return of unused order forms.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to §§ 301.45 or 301.46 of this chapter as to any controlled substance listed in schedule I or II, he shall return all unused order forms for such substance to the nearest office of the Bureau.

§ 305.15 Cancellation and voiding of order forms.

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the supplier in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

§ 305.16 Interim use of IRS order forms and requisitions.

(a) Existing order forms (IRS Form 2513) will be valid until April 30, 1972, for transactions of controlled substances listed in schedule I and II. Purchasers using existing IRS Forms 2513 after April 30, 1971, must place the registration number assigned by the Bureau on the form in the block which contains the name, address, old IRS registration, and class of registration. Registrants who obtain BND Form 222c, but still possess IRS order forms, should not discard the IRS Forms, but instead draw a line thru the unused forms and print "Void" across the line. Voided forms must be maintained

for at least 2 years in the manner prescribed in § 305.13.

(b) Effective May 1, 1971, only the Bureau will issue order forms. A purchaser desiring order forms (BND Form 222c) may obtain them by using IRS Form 679 found in the back of his current IRS order from book. In utilizing IRS Form 679, the registration number assigned by the Bureau must be placed in section 8 of the requisition form and the requisition forwarded to Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. IRS Form 679 will not be valid after April 30, 1972.

(c) An existing power of attorney filed for Internal Revenue Service order forms will be valid until the provisional registration of the registrant expires.

PART 306—PRESCRIPTIONS

Sec.

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306.02 Definitions.
306.03 Persons entitled to issue prescriptions.
306.04 Purpose of issue of prescription.
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CONTROLLED SUBSTANCES LISTED IN SCHEDULE III AND IV

306.21 Requirement of prescription.
306.22 Refilling of prescriptions.
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306.24 Filing prescriptions.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE V

306.31 Requirement of prescription.
306.32 Dispensing without prescription.

AUTHORITY: The provisions of this Part 306 issued under secs. 301, 309, 501(b), 84 Stat. 1253, 1260, 1271; 21 U.S.C. 821, 829, 871(b).

GENERAL INFORMATION

§ 306.01 Scope of Part 306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 306.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801).

(b) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(c) The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(d) The term "pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., a pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

(e) The term "prescription" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (E.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

(e) The term "register" or "registered" means a person registered under section 303 of the Act (21 U.S.C. 823).

(f) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or § 301.02 of this chapter.

§ 306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and

(2) either registered or exempted from registration pursuant to § 301.25 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

§ 306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

§ 306.05 Manner of issuance of prescriptions.

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

§ 306.06 Persons entitled to fill prescriptions.

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

§ 306.07 Dispensing of narcotic drugs for maintenance purposes.

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research" in section 308(e) of the Act (21 U.S.C. 828(e)): *Provided*, That approval is obtained prior to the initiation of such a program by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau for drug control requirements, and that the clinical investigation thereafter accords with such approval, as required in § 130.44 of this title.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

§ 306.11 Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in paragraph (d) of this section.

(b) An individual practitioner may administer or dispense a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to § 306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in § 1.110 of this title, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Bureau if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

§ 306.12 Refilling prescriptions.

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

§ 306.13 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

§ 306.14 Labeling of substances.

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

§ 306.15 Filing of prescriptions.

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 304.04(d) of this chapter.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III AND IV

§ 306.21 Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 306.05, except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense a controlled substance listed in schedule III or IV in the course of his professional practice without a prescription, subject to § 306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 306.05 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 306.07.

§ 306.22 Refilling of prescriptions.

No prescription for a controlled substance listed in schedule III or IV shall be filled or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription (or on another appropriate uniformly maintained record, such as medication records, which indicates prescription refills), initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription he shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in § 306.21 which shall be a new and separate prescription.

§ 306.23 Labeling of substances.

The pharmacist filling a prescription for a controlled substance listed in schedule III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

§ 306.24 Filing prescriptions.

All prescriptions for controlled substances listed in schedules III and IV shall be kept in accordance with § 304.04(d) of this chapter.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE V

§ 306.31 Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in schedule V pursuant to a prescription as required for controlled substances listed in schedules III and IV in § 306.21. A prescription for a controlled substance listed in schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with § 306.23 and file the prescription in accordance with § 306.24.

(b) An individual practitioner may administer or dispense a controlled sub-

stance listed in schedule V in the course of his professional practice without a prescription, subject to § 306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 306.05 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 306.07.

§ 306.32 Dispensing without prescription.

A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such distribution is made only by a pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in his section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such substance containing opium, nor more than 120 cc. (4 ounces) of any other controlled substance listed in schedule V, may be distributed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance listed in schedule V not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances listed in schedule V (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who distributed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

PART 307—MISCELLANEOUS

GENERAL INFORMATION

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307.02 Application of State law and other Federal law.
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SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION CONTROLLED SUBSTANCES

307.11 Emergency distribution by a dispenser.
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DISPOSAL OF CONTROLLED SUBSTANCES

307.21 Procedure for disposing of controlled substances.
307.22 Disposal of controlled substances by the Bureau.

SPECIAL EXEMPT PERSONS

307.31 Native American Church.

AUTHORITY: The provisions of this Part 307 issued under secs. 301, 302(d), 501(b), 84 Stat. 1253, 1271; U.S.C. 821, 822(d), 871(b).

GENERAL INFORMATION

§ 307.01 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in § 301.02 of this chapter.

§ 307.02 Application of State law and other Federal law.

Nothing in Parts 301–308, 311, 312, or 316 of this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

§ 307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of Parts 301–308, 311, 312, or 316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. The Director may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 307.11 Emergency distribution by a dispenser.

(a) In the event of an emergency, a dispenser may distribute (without being registered to distribute) a controlled substance to a second dispenser in order for the second dispenser to dispense the substance, provided that:

(1) The amount distributed does not exceed to the amount required by the second dispenser for immediate dispensing;

(2) The distribution is recorded as a dispensing by the first dispenser, and the receipt as a distribution received by the second dispenser, and each dispenser retains a signed receipt of the distribution;

(3) The second dispenser is registered under the Act to dispense the controlled substance to be distributed to him; and

(4) If the substance is listed in schedule I or II, an order form is used as required in Part 305 of this chapter.

(b) For purposes of this section, an emergency shall mean a situation where a quantity of a controlled substance must be dispensed to a person who does not have an alternative source for such substance reasonably available to him and the dispenser cannot obtain such substance through normal distribution channels within the time required to meet the need of the person for such substance.

§ 307.12 Distribution of aqueous or oleaginous solutions by a pharmacist.

A pharmacist who is registered to dispense or is covered by another person's registration to dispense may distribute (without being registered to distribute) to a registered practitioner, an aqueous or oleaginous solution, in a quantity not exceeding 1 ounce at any one time, containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, to be used by the practitioner in the course of his professional practice for administration to a patient, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number of the pharmacist (or other registered person), and the name, address, and registration number of the practitioner. In the case of a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of this chapter and be maintained as the written record of the transaction.

§ 307.13 Distribution to supplier.

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of this

chapter and be maintained as the written record of the transaction.

§ 307.14 Distribution upon discontinuance or transfer of business.

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Certificate of Registration, and any unexecuted order forms in his possession, to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005 for cancellation. Any controlled substances in his possession may be disposed of either in accordance with § 307.21 or by transfer to another registrant. If the registrant desires to transfer the substance to another registrant, he shall take an inventory of all controlled substances which he desires to transfer and submit this inventory, together with his name, address, and registration number, and the name, address, and registration number of the proposed transferee, to the Regional Director of the Bureau in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Regional Director does not notify the registrant that the transfer should be postponed or canceled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in schedule I or II must be transferred pursuant to order forms in accordance to Part 305 of this chapter. Schedule III, IV, and V substances will be transferred in accordance to the inventory prepared by the registrant and submitted to the Regional Director. If the Regional Director denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substance in accordance with § 307.21 or transfer the substances to another registrant in accordance with this section and/or the instructions of the Regional Director.

(b) In the case of registrants required to make reports pursuant to Part 304 of this chapter, a report marked "Final" will be prepared and submitted by the transferor registrant showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, provided that no further transactions involving controlled substances are consummated by him. The initial report of the transferee registrant shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor registrant, and the substances transferred to him shall be reported as receipts in his initial report.

§ 307.15 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to Part 303 of this chapter (if such substance or class is listed in schedule I or II) shall be exempt from the requirement of registration pursuant to Part 301 of this chapter and, if such incidentally manufactured substance is listed in schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to Part 303 of this chapter, if such substances are disposed of in accordance with § 307.21.

DISPOSAL OF CONTROLLED SUBSTANCES

§ 307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Regional Director of the Bureau in the region in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant required to make reports pursuant to Part 304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Regional Director of the Bureau in his region;

(2) If the person is a registrant not required to make reports pursuant to Part 304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on BND Form 41, and submit three copies of that form to the Regional Director in his region; and

(3) If the person is not a registrant, he shall submit to the Regional Director a letter stating:

(1) The name and address of the person;

(2) The name and quantity of each controlled substance to be disposed of;

(3) How the applicant obtained the substance, if known; and

(4) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Regional Director shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Bureau or to the nearest office of the Bureau;

(3) By destruction in the presence of an agent of the Bureau or other authorized person; or

(4) By such other means as the Regional Director may determine to assure that the substance does not become available to unauthorized persons.

(c) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

§ 307.22 Disposal of controlled substances by the Bureau.

Any controlled substance delivered to the Bureau under § 307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Director, if, in his opinion, there exists a medical or scientific need therefor.

SPECIAL EXEMPT PERSONS

§ 307.31 Native American Church.

The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

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AUTHORITY: The provisions of this Part 308 issued under secs. 201, 202, 501(b), 84

Stat. 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1271, 21 U.S.C. 811, 812, 871(b).

GENERAL INFORMATION

§ 308.01 Scope of Part 308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812), as they are changed, updated, and republished from time to time, are set forth in this part.

§ 308.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "hearing" means any hearing held pursuant to this part for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act.

(c) The term "isomer" means, except as used in § 308.11(d), the optical isomer. As issued in § 308.11(d), the term "isomer" means the optical, position or geometric isomer.

(d) The term "interested person" means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act.

(e) The term "proceeding" means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act, commencing with the publication by the Director of the proposed rule, amended rule, or repeal in the FEDERAL REGISTER.

(f) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and § 301.02 of this chapter.

§ 308.03 Bureau controlled substances code number.

(a) Controlled substances, a basic class thereof, listed in schedules I through IV have been assigned a "Bureau Controlled Substances Code Number" for purposes of identification of such substances on certain Certificates of Registration issued by the Bureau pursuant to § 301.44 of this chapter and on certain order forms issued by the Bureau pursuant to § 305.05(d) of this chapter. Certain applicants for registration must include the appropriate numbers on the application as required in § 301.32(d) and applicants for procurement and/or individual manufacturing quotas must include the appropriate number on the application as required in §§ 303.12(b) and 303.22(a).

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Bureau Controlled Substances Code Number for any purpose.

SCHEDULES

§ 308.11 Schedule I.

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau Controlled Substances Code Number set forth opposite it.

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol	9601
(2) Allylprodine	9602
(3) Alphacetylmethadol	9603
(4) Alphameprodine	9604
(5) Alphamethadol	9605
(6) Benzethidine	9606
(7) Betacetylmethadol	9607
(8) Betameprodine	9608
(9) Betamethadol	9609
(10) Betaprodine	9611
(11) Clonitazene	9612
(12) Dextromoramide	9613
(13) Dextrorphan	9614
(14) Diampromide	9615
(15) Diethylthiambutene	9616
(16) Dimenoxadol	9617
(17) Dimepheptanol	9618
(18) Dimethylthiambutene	9619
(19) Dioxaphetyl butyrate	9621
(20) Dipipanone	9622
(21) Ethylmethylthiambutene	9623
(22) Etonitazene	9624
(23) Etoxeridine	9625
(24) Furethidine	9626
(25) Hydroxypethidine	9627
(26) Ketobemidone	9628
(27) Levomoramide	9629
(28) Levophenacylmorphan	9631
(29) Morpheridine	9632
(30) Noracymethadol	9633
(31) Norlevorphanol	9634
(32) Normethadone	9635
(33) Norpipanone	9636
(34) Phenadoxone	9637
(35) Phenampromide	9638
(36) Phenomorphan	9647
(37) Phenoperidine	9641
(38) Piritramide	9642
(39) Proheptazine	9643
(40) Properidine	9644
(41) Racemoramide	9645
(42) Trimeperidine	9646

(c) *Opium derivatives.* Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine	9319
(2) Acetyldihydrocodeine	9051
(3) Benzylmorphine	9052
(4) Codeine methylbromide	9070
(5) Codeine-N-Oxide	9053
(6) Cyprenorphine	9054
(7) Desomorphine	9055
(8) Dihydromorphine	9145
(9) Etorphine	9056
(10) Heroin	9200
(11) Hydromorphinol	9301
(12) Methyldesorphine	9302
(13) Methyldihydromorphine	9304
(14) Morphine methylbromide	9305
(15) Morphine methylsulfonate	9306
(16) Morphine-N-Oxide	9307
(17) Myrophine	9308
(18) Nicocodeine	9309
(19) Nicomorphine	9312
(20) Normorphine	9313
(21) Pholcodine	9314
(22) Thebacon	9315

(d) *Hallucinogenic substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 3,4-methylenedioxy amphetamine	7400
(2) 5-methoxy-3,4-methylenedioxy amphetamine	7401
(3) 3,4,5-trimethoxy amphetamine	7390
(4) Bufotenine	7433
Some trade and other names: 3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; *N,N*-dimethylserotonin; 5-hydroxy-*N*-dimethyltryptamine; mappine.	
(5) Diethyltryptamine	7434
Some trade and other names: *N,N*-Diethyltryptamine; DET.	
(6) Dimethyltryptamine	7435
Some trade or other names: DMT	
(7) 4-methyl-2,5-dimethoxyamphetamine	7395
Some trade and other names: 4-methyl-2,5-dimethoxy-α-methylphenethylamine; "DOM"; and "STP".	
(8) Ibogaine	7260
Some trade and other names: 7-Ethyl-6,6α,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido (1′,2′:1,2 azepino 4,5-b) indole; tabernanthe iboga.	
(9) Lysergic acid diethylamide	7315
(10) Marihuana	7360
(11) Mescaline	7381
(12) Peyote	7415
(13) N-ethyl-3-piperidyl benzilate	7482
(14) N-methyl-3-piperidyl benzilate	7484
(15) Psilocybin	7437
(16) Psilocyn	7438
(17) Tetrahydrocannabinols	7370
Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:	
Δ^1 cis or trans tetrahydrocannabinol, and their optical isomers.	
Δ^6 cis or trans tetrahydrocannabinol, and their optical isomers.	
$\Delta^{3,4}$ cis or trans tetrahydrocannabonil tetrahydrocannabinol, and its optical isomers.	
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)	

§ 308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, including the following:

(i) Raw opium	9600
(ii) Opium extracts	9610
(iii) Opium fluid extracts	9620
(iv) Powdered opium	9639
(v) Granulated opium	9640
(vi) Tincture of opium	9630
(vii) Apomorphine	9030
(viii) Codeine	9050
(ix) Ethylmorphine	9190
(x) Hydrocodone	9193
(xi) Hydromorphone	9194
(xii) Metopon	9260
(xiii) Morphine	9300
(xiv) Oxycodone	9143
(xv) Oxymorphone	9652
(xvi) Thebaine	9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (1) of this paragraph, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).

(c) *Opiates.* Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine	9010
(2) Anileridine	9020
(3) Bezitramide	9800
(4) Dihydrocodeine	9120
(5) Diphenoxylate	9170
(6) Fentanyl	9801
(7) Isomethadone	9226
(8) Levomethorphan	9210
(9) Levorphanol	9220
(10) Metazocine	9240
(11) Methadone	9250
(12) Methadone–Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane	9254
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid	9802
(14) Pethidine	9230
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
(18) Phenazocine	9715
(19) Piminodine	9730
(20) Racemethorphan	9732
(21) Racemorphan	9733

(d) *Methamphetamine.* Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers 1400

§ 308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau Controlled Substances Code Number set forth opposite it.

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers	1100
(2) Phenmetrazine and its salts	1630
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers	1105
(4) Methylphenidate	1726

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid	2100
(2) Chlorhexadol	2510
(3) Glutethimide	2550
(4) Lysergic acid	7300
(5) Lysergic acid amide	7310
(6) Methyprylon	2575
(7) Phencyclidine	7471
(8) Sulfondiethylmethane	2600
(9) Sulfonethylmethane	2605
(10) Sulfonmethane	2610

(d) *Nalorphine* 9400

(e) *Narcotics drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium	9803
(2) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9804
(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium	9805
(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9806
(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9807
(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9808
(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams and not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9809
(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9810

§ 308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Bureau Controlled Substances Code Number set forth opposite it.

(b) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Barbital	2145
(2) Chloral betaine	2460
(3) Chloral hydrate	2465
(4) Ethchlorvynol	2540
(5) Ethinamate	2545
(6) Methohexital	2264
(7) Meprobamate	2820
(8) Methylphenobarbital	2250
(9) Paraldehyde	2585
(10) Petrichloral	2591
(11) Phenobarbital	2285

§ 308.15 Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) *Narcotic drugs containing nonnarcotic active medicinal ingredients.* Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation

valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams and not more than 10 milligrams per dosage unit.

(2) Nor more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

EXCLUDED NONNARCOTIC SUBSTANCES

§ 308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) An application for an exclusion under this section shall be handled by the Director, in determining whether the substance shall be excluded, in the manner prescribed for petitions to classify a substance on a schedule set forth in §§ 308.41–308.49 of this chapter.

§ 308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)):

Trade name or other designation	Composition	Manufacturer or supplier
Amodrine	Tablet: Phenobarbital, 8 mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G. D. Searle & Co.
Bronkaid	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Drew Pharmacal Co., Inc.
Bronkolixir	Elixir (5 cc): Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl guaiacolate, 50 mg.; theophylline, 15 mg.; chlorpheniramine maleate, 1 mg.	Breon Laboratories Inc.
Bronkotabs	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Do.
Beckman Buffer B–1	Packet: Diethyl Barbituric Acid, 1.84 gm.; sodium diethyl barbiturate, 10.30 gm. (for use with Beckman Model R paper electrophoresis system).	Spinco Division, Beckman Instruments, Inc.
Beckman Buffer B–2	Packet: Diethyl Barbituric Acid, 2.76 gm.; sodium diethyl barbiturate, 15.40 gm. (for use with Beckman Model R paper electrophoresis system).	Do.
Primatene	Tablet: Phenobarbital, ¼ gr.; ephedrine, ⅜ gr.	Whitehall Laboratories.
Tedral	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral Anti-H	Tablet: Phenobarbital, 8 mg.; chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Tedral one-half strength	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg.; ephedrine hydrochloride, 12 mg.	Do.
Tedral Pediatric Suspension	Suspension (5 cc): Phenobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength.	Suppository: Phenobarbital, 16 mg.; theophylline, 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tedral suppositories regular strength.	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Verequad	Tablet: Phenobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 100 mg.	Knoll Pharmaceutical Co.
Verequad	Suspension (5 cc): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 50 mg.	Do.

EXCEPTED STIMULANT OR DEPRESSANT COMPOUNDS

§ 308.31 Application for exception of a stimulant or depressant compound.

(a) Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in § 308.13 (b) or (c), or in § 308.14, or in § 308.15, excepted from the application of all or any part of the Act, pursuant to section 202(d) of the Act (21 U.S.C. 812(d)), may apply to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washingtin, D.C. 20537, for such exception.

(b) An application for an exception under this section shall contain the following information:

(1) The complete quantitative composition of the dosage form.

(2) Description of the unit dosage form together with complete labeling.

(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

(4) Details of synergisms and antagonisms among ingredients.

(5) Deterrent effects of the noncontrolled ingredients.

(6) Complete copies of all literature in support of claims.

(7) Reported instances of abuse.

(8) Reported and anticipated adverse effects.

(9) Number of dosage units produced for the past 2 years.

(c) An application for an exception under this section shall be handled in the manner prescribed for petitions to classify a substance on any schedule set forth in §§ 308.41–308.49 of this chapter.

§ 308.32 Excepted compounds.

(a) Until criteria are adopted by the Bureau by which the Director may determine whether to except any compound, mixture, or preparation containing any depressant or stimulant substance listed in § 308.13 (b) or (c), or in § 308.14, or in § 308.15, from the application of all or any part of the Act pursuant to section 202(d) of the Act (21 U.S.C. 812(d)), the drugs set forth in paragraph (b) of this section have been excepted by the Director from application of the sections 305, 307, 308, and 309 of the Act (21 U.S.C. 825, 827–9, 952–4), 1002, 1003, and 1004 for administrative purposes only. The excepting of these drugs by the Director should not be construed as an adoption or rejection of the criteria by which these drugs were originally excepted. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

(b) The following drugs in dosage unit form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant, or hallucinogenic effect, and which are restricted by law to dispensing on prescription, are excepted from the application of sections 305, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 825, 827–9, 952–4):

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A.	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Alased	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried, 7½ gr.; magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.
Alcitex	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/5000 gr.; calcium carbonate, 3½ gr.; magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories Inc.
Alhydrox	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply.
Alkasans	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P. J. Noyes Co.
Alsical	Powder (60 gr.): Phenobarbital, ¼ gr.; belladonna extract, ⅛ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hydroxide gel, dried, 10 gr.	Dorsey Laboratories.
Alubelap	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 300 mg.; belladonna extract, 4 mg.	Haack Laboratories, Inc.
Aludrox SA Suspension	Suspension (5 cc.): Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Aludrox SA Tablets	Tablet: Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Do.
Alu-Mag	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ⅛ gr.	Norsal Laboratories, Inc.
Alumazen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg.; aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate, and kaolin with phenobarbital and atropine sulfate.	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, colloidal, 2 gr.; atropine sulfate, 1/300 gr.	Buffalo Pharmaceutical Supply Corp.
Aminodrox with Phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm.; aluminum hydroxide gel, dried, 0.12 gm.	The S. E. Massengill Co.
Aminodrox-Forte with Phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	Do.
Aminophylline and Amytal	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly Co.
Aminophylline with pentobarbital.	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G. D. Searle & Co.
Aminophylline and phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	The Zemmer Co.
Do	Tablet: Phenobarbital, ¼ gr.; aminophylline, 100 mg.	The Blue Line Chemical Co.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 16 mg.; aminophylline, 100 mg.	H. E. Dubin Laboratories, Inc.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	G. D. Searle & Co.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	Do.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	Do.
Amobarbital and PETN	Capsule: Amobarbital, 50 mg.; pentaerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with Butabarbital Sodium (AMPYROX).	Tablet: Butabarbital sodium, 15 mg.; scopolamine methylnitrate, 2 mg.	Paul B. Elder Co., Inc.
Ampyrox with Butabarbital Sodium, Elixir.	Elixir (5 cc.): Butabarbital sodium, 10 mg.; scopolamine methylnitrate, 1 mg.	Do.
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr.; hyoscine hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmacal, Inc.
Amsodyne	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ⅛ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder Co., Inc.
Antacia No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic	Tablet (purple): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyoscine hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-Enzyme	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0519 mg.; homatropine methylbromide, 0.2885 mg.; hyoscine hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Hydrex Co., Inc.
Antrocol	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-Plus, Children	Suppository: Pentobarbital sodium, 3/8 gr.; theophylline, 1⅞ gr.	The Wm. A. Webster Co.
Aqualin-Plus No. 1	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 3¾ gr.	Do.
Aqualin-Plus No. 2	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-Plus No. 2A	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 7½ gr.	Do.
Asmabar	Tablet: Butabarbital, 20 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Asmacol	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanolamine hydrochloride, 25 mg.; chlorpheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.
Asperease, Modified with Phenobarbital.	Tablet: Phenobarbital, 0.008 gm.; acetylsalicyclic acid, 0.5 gm.	P. J. Noyes Co.
Atropal	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/500 gr.; magnesium trisilicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Mallinckrodt Chemical Works.
Atrosilital	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Banthine with Phenobarbital	Tablet: Phenobarbital, 15 mg.; methantheline bromide, 50 mg.	G. D. Searle & Co.
Barbatro No. 1	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S. E. Massengill Co.
Barbatro No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscine hydrobromide, 0.007 mg.; homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna Elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Mallinckrodt Chemical Works.
Barbidonna Tablets	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Do.
Barboma Elixir	Elixir (100 cc.): Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma Tablets	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/48 gr.	Do.
Bardase	Tablet or elixir (4 cc.): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyoscine hydrobromide, 0.007 mg.; atropine, 0.020 mg.; Taka-Diastase, 162.0 mg.	Parke, Davis & Co.
Bar-Don Elixir	Elixir (30 cc.): Phenobarbital, 100 mg.; hyoscyamine hydrobromide, 0.60 mg.; hyoscine hydrobromide, 0.042 mg.; atropine sulfate, 0.12 mg.	Warren-Teed Pharamaceuticals Inc.
Bar-Don Tablets	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscine hydrobromide, 0.007 mg.; atropine sulfate, 0.020 mg.	Do.
Belap No. 0	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Haack Laboratories, Inc.
Belap No. 1	Tablet: Phenobarbital, 15 mg.; belladonna extract, 8 mg.	Do.
Belap Ty-Med	Tablet: Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Do.
Belladenal	Tablet: Phenobarbital, 50 mg.; bellafoline, 0.25 mg.	Sandoz Pharmaceuticals.
Do	Elixir (15 cc.): Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Do.
Bellatol Elixir	Elixir (5 cc.): Butabarbital sodium, 20 mg.; tincture belladonna, 0.83 cc.	The Zemmer Co.

Trade name or other designation	Composition	Manufacturer or supplier
Bellergal	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg.; levorotatory alkaloids of belladonna, 0.1 mg.	Sandoz Pharmaceuticals.
Do	Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Do.
Beplete with Belladonna Elixir.	Elixir (4 cc.): Phenobarbital, 15 mg.; vitamin B_1, 1.5 mg.; vitamin B_2, 1 mg.; vitamin B_6, 0.33 mg.; vitamin B_{12}, 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories.
Bexadonna	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscine hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals.
Bilamide	Tablet: Phenobarbital, ⅛ gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr.; homatropine methylbromide, ¼₈ gr.	Norgine Laboratories, Inc.
Binitrin	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.0 mg.	The Vale Chemical Co., Inc.
Bioxatphen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital.	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, ⅙ gr.	The Bernard Co.
Buffadyne A–S	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with Barbiturates	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopolamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B. F. Ascher & Co., Inc.
Burrizem	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.
Butabarbital and hyoscyamine sulfate.	Tablet or elixir (5 cc.): Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg.	McNeil Laboratories, Inc.
Do	Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	Do.
Butibel	Tablet or elixir (5 cc.): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.; hyoscine hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.).	Do.
Butibel R–A	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-Gel Suspension	Suspension (15 cc.): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.187 mg.); activated attapulgite, 1.5 mg.; pectin, 75 mg.	Do.
Butibel-Gel Tablets	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 500 mg.; pectin, 45 mg.	Do.
Butibel-Zyme	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic emzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butigetic	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.
Cafergot P–B	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg.	Sandoz Pharmaceuticals.
Do	Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Do.
Cal-Ma-Phen	Tablet: Phenobarbital, ¼ gr.; calcium-carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, ⅓₆₀₀ gr.	Physicians Supply Co.
Cantil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P. J. Noyes Co.
Cardalin-Phen	Tablet: Phenobarbital, ¼ gr.; aminophylline, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ½ gr.	Mallinckrodt Chemical Works.
Cardilate-P	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarace	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racephedrine, 20 mg.	Warner-Chilcott Laboratories.
Co-Elorine 25	Capsule: Amobarbital, 8 mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, Special	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg.; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Corenil	Tablet: Racemic methamphetamine hydro chloride, 1.25 mg.; clistin (carbinoxamine maleate), 2 mg.; belladonna extract, 8 mg.	McNeil Laboratories, Inc.
Covadil	Tablet: Butabarbital sodium, 20 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.
Dainite	Tablet: Pentobarbital sodium, ¼ gr. aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Mallinckrodt Chemical Works.
Dainite-KI	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Night	Tablet: Phenobarbital, ⅜ gr.; pentobarbital sodium, ½ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Daricon PB	Tablet: Phenobarbital, 15 mg.; oxyphencyclimine hydrochloride, 5 mg.	Pfizer Laboratories.
Diatraegus	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, ½₂₅₀ gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims.	Buffington's, Inc.
Dia-Tropine	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, ⅓₆₀₀ gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with Phenobarbital	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do	Capsule: Phenobarbital, ½ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories.
Donabarb	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ⅛ gr.	Paul B. Elder Co., Inc.
Donaphen, New Special Donaphen.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krone Co.
Donna-Sed Elixir	Elixir (5 cc.): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hysocine hydrobromide, 0.0065 mg.	North American Pharmacal, Inc.
Donnasep	Tablet: Phenobarbital, 8.1 mg.; phenazopyridine hydrochloride, 50.0 mg., methenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyoscine hydrobromide, 0.0033 mg.	A. H. Robins Co., Inc.
Donphen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 6 μg.	Lemmon Pharmacal Co.
Dormitol-HM	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, ¼₆₄ gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with Phenobarbital	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.
Edrisal	Tablet: Dextroamphetamine sulfate, 2.5 mg.; aspirin, 0.16 gm.; phenacetin 0.16 gm.	Smith Kline & French Laboratories.
Elmaloin with Phenobarbital	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital.	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	The Vale Chemical Co., Inc.

Trade name or other designation	Composition	Manufacturer or supplier
Ephedrine sulfate and phenobarbital.	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with Phenobarbital.	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	P. J. Noyes Co.
Ercafital	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 50 mg.	The Blue Line Chemical Co.
Ethrava-trate	Tablet: Mephobarbital, 10 mg.; pentaerythrityl tetranitrate, 20 mg.; ethaverine hydrochloride, 30 mg.	North American Pharmacal, Inc.
Eu-Phed-Amin	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceuticals Inc.
Eu-Phed-Ital	Tablet: Phenobarbital sodium, 30 mg.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Do.
Fensobel	Tablet: Phenobarbital, 8.1 mg.; belladonna extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 203.5 mg.; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin & Pharmaceutical Corp.
Franol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories.
Genegesic Capsules	Capsule: Methamphetamine hydrochloride, 1.2 mg.; chlorpheniramine maleate, 3.8 mg.; phenacetin, 120.0 mg.; salicylamide, 180.0 mg.; caffeine, 30.0 mg.; ascorbic acid, 50.0 mg.	General Pharmaceutical Products, Inc.
Homechol	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg.; ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homopent	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg.; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
Hovizyme	Tablet: Methamphetamine hydrochloride, 0.5 mg.; conjugated estrogen-equine, 0.125 mg.; methyl testosterone, 1.25 mg.; amylase, 10.0 mg.; protease, 5.0 mg.; cellulase, 2.0 mg.; nicotinyl alcohol tartrate, 7.5 mg.; dehydrocholic acid, 50.0 mg.; ascorbic acid, 50.0 mg.; ferrous fumarate, 6.0 mg.	Ayerst Laboratories.
H-P-A (Modified)	Tablet: Phenobarbital, ¼ gr.; aspirin, 5 gr.; extract hyoscyamus, ⅛ gr.	Paine Drug Co.
Hybephen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	The S. E. Massengil Co.
Hybephen Elixir	Elixir (5 cc.): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	Do.
Hydrochol Plus	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.8 mg.; ox bile desiccated, 50 mg.	Paul B. Elder Co., Inc.
Hytrona Antispasmodic Elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore.
Hytrona Antispasmodic Tablets.	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Ilocalm	Tablet: Mephobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; *d*-calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with Phenobarbital	Tablet: Phenobarbital, 15 mg.; isosorbide dinitrate, 10 mg.	Ives Laboratories Inc.
Isufranol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories.
Isufranol, Mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.
Isuprel Compound Elixir	Elixir (15 cc.): Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 45 mg.; potassium iodide, 150 mg.	Do.
Kaphebel	Tablet: Phenobarbital, ⅛ gr.; belladonna root, ¼ gr.; kaolin colloidal, 7½ gr.	Paul B. Elder Co., Inc.
Kanumodic	Tablet: Pentobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulase, 9 mg.; pancrestin, 500 mg.; glutamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories.
Kavatrate	Tablet: Phenobarbital sodium, ¼ gr.; veratrum veride, ¼ gr.; mistletoe, ½ gr.; hawthorn tincture, 30 minims; sodium nitrite, 1 gr.	Key Pharmacal Co.
Kie with Phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide, 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Kiophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 150 mg.; potassium iodide, 125 mg.	G. D. Searle & Co.
Luftodil Suspension	Suspension (5 cc.): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 100 mg.	Mallinckrodt Chemical Works.
Luftodil Tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 200 mg.	Do.
Lufyllin-EP	Tablet: Phenobarbital, 16 mg.; lufyllin (dyphylline), 100 mg.; ephedrine hydrochloride; 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound.	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malglyn Compound	Tablet or suspension (5 cc.): Phenobarbital, 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Manniphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Manniphen with Rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital.	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	The Blue Line Chemical Co.
Maxitol	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.
Mediatric	Tablet or capsule: Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5. mg.	Ayerst Laboratories.
Mediatric Liquid	Solution (15 cc.): Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5. mg.	Do.
Meprane Phenobarbital	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick.
Mesopin-PB	Tablet or elixir (5 cc.): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.
Metamine with Butabarbital	Tablet: Butabarbital, 16.2 mg.; trolnitrate phosphate, 2 mg.	Pfizer Laboratories.
Do	Tablet: Butabarbital, 48.6 mg.; trolnitrate phosphate, 10 mg.	Do.
Mexal	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The S. E. Massengill Co.
Milprem-200	Tablet: Meprobamate 200 mg. Conjugated Estrogens—equine 0.4 mg.	Wallace Pharmaceuticals.
Milprem-400	Tablet: Meprobamate 400 mg. Conjugated Estrogens—equine 0.4. mg.	Do.
Milpath-200	Tablet: Meprobamate 200 mg. Tridihexethyl Chloride, 25 mg.	Do.
Milpath-400	Tablet: Meprobamate 400 mg. Tridihexethyl Chloride, 25 mg.	Do.
Miltrate-10	Tablet: Meprobamate 200 mg. Pentaerythritol tetranitrate, 10 mg.	Do.
Miltrate-20	Tablet: Meprobamate 200 mg. Pentaerythritol tetranitrate, 20 mg.	Do.
Monomeb	Tablet: Mephobarbital, 32 mg.; penthienate bromide, 5 mg.	Winthrop Laboratories.
Mudrane	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloride, 16 mg.	Wm. P. Poythress & Co., Inc.
Mudrane GG Elixir	Elixir (5 cc.): Phenobarbital, 5.4 mg.; theophylline 20 mg.; ephedrine hydrochloride, 4 mg.; glyceryl guaiacolate, 26 mg.	Do
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.
Natrona Compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrite, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg., homatropine methylbromide, 1.2 mg.	Pitman-Moore.
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate, 0.5 gm.	The S. E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacal Co.
Nophesan Tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P. J. Noyes Co.

Trade name or other designation	Composition	Manufacturer or supplier
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg ; calcium lactate, 162 mg.	Lemmon Pharmacal Co.
Oxsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrochloic acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan monooleate, 160 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal Elixir	Elixir (5 cc,): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, Half Strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric Piptal Antipyretic	Solution (0.6 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.
Pediatric Piptal with Phenobarbital.	Solution (0.5 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 2 mg.	Do.
Pencetylon	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co., Inc.
Pentaerythrityl tetranitrate with phenobarbital.	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentratrol with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmacal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbuzem	Tablet: Butabarbital sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner-Chilcott
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with Phenobarbital SA.	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallylbarbituric acid, 16 mg.; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophyline, 100 mg.	Buffington's, Inc.
Phenaphen Plus	Tablet: Phenobarbital, 16.2 mg.; phenacetin, 194 mg.; aspirin, 162 mg.; hyoscyamine sulfate, 0.031 mg.; pheniramine maleate, 12.5 mg.; phenylephrine hydrochloride, 10 mg.	A. H. Robins Co., Inc.
Phenobarbital and atropine	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/300 gr.	The Blue Line Chemical Co.
Do	do	Meyers & Co.
Do	do	Paine Drug Co.
Do	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/250 gr.	The Vale Chemical Co., Inc.
Phenobarbital with atropine sulfate.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No. 2.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	Do.
Phenobarbital and atropine sulfate.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Buffington's Inc.
Phenobarbital & Atropine No. 1.	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore.
Phenobarbital & Atropine No. 2.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.65 mg.	Do.
Phenobarbital and Atropine Tablets.	Tablet: Phenobarbital, 8 mg.; atropine sulfate 1/1000 gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 1/300 gr.	Do.
Phenobarbital and Atropine Tablets No. 2.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and Atropine Tablets No. 3.	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/300 gr.	Do.
Phenobarbital and belladonna	Tablet: Phenobarbital, ¼ gr.; belladonna leaves ½ gr. (total alkaloids 0.0015 gr.).	The Vale Chemical Co., Inc.
Do	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ⅛ gr.	Paine Drug Co.
Do	Tablet: Phenobarbital, 16 mg.; belladonna extract, 8 mg.	Eli Lilly and Co.
Phenobarbital and Belladonna No. 2.	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ⅛ gr. (alkaloids 0.00156 gr.).	The Upjohn Co.
Phenobarbital with mannitol hexanitrate.	Tablet: Phenobarbital, 7.5 mg., mannitol hexanitrate 15 mg.; ascorbic acid powder, 25 mg.; rutin, 25 mg	Paul B. Elder Co., Inc. (Harold M. Harter, D.V.M.)
Phenobarbital and mannitol hexanitrate.	Tablet; Phenobarbital, ¼ gr.; mannitol hexanitrate, ⅛ gr.	Meyer Drug & Surgical Supply Co.
Phenobarbital Sodium Atropine No. 1.	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 μg.	McNeil Laboratories, Inc.
Phenobarbital Sodium Atropine No. 2.	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 μg.	McNeil Laboratories, Inc.
Phenobarbital Sodium Atropine No. 3.	Tablet: Phenobarbital sodium, 20 mg.; atropine sulfate, 200 μg.	Do.
Phenobarbital and sodium nitrite.	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	P. J. Noyes Co.
Phenobarbital Theocalcin	Tablet: Phenobarbital, 15 mg.; theobromine calcium salicylate, 0.5 gm.	Knoll Pharmaceutical Co.
Phenodonna Tablets	Tablet: Phenobarbital, ¼ gr.; tincture belladonna, 6 minims.	Flint Medical & Surgical Supply Co.
Phenodrox	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/300 gr.; magnesium trisilicate, 4 gr.; aluminum hydroxide gel, dried, 4 gr.	North American Pharmacal Inc.
Phyldrox	Tablet: Phenobarbital, 15 mg.; neothylline, 100 mg.; ephedrine sulfate, 25 mg.	Lemmon Pharmacal Co.
Piptal PHB Elixir	Elixir (5cc.): Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Lakeside Laboratories, Inc.
Piptal PHB Tablets	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Prantal with Phenobarbital	Tablet: Phenobarbital, 16 mg.; diphemanil methylsulfate, 100 mg.	Schering Corp.
Premarin with Phenobarbital	Tablet: Phenobarbital, 32 mg.; conjugated estrogens-equine, 0.625 mg.	Ayerst Laboratories.
Probanthine with phenobarbital.	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	G. D. Searle & Co.
Probital	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	Do.
Propenite	Tablet: Phenobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	The Zemmer Co.
Prydonnal Spansule	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg., scopolamine hydrobromide, 0.035 mg.).	Smith Kline & French Laboratories.
Quadrinal	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride 24 mg.; theophyline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Knoll Pharmaceutical Co.
Do	Suspension (5 cc.): Phenobarbital, 12 mg.; ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate, 65 mg.; potassium iodide, 160 mg.	Do.
Quintrate with Nitroglycerin and Phenobarbital.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.; nitroglycerin, 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Quintrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Do.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Robinul-PH	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A. H. Robins Co., Inc.
Robinul-PH Forte	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Ruhexatal	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; ascorbic acid, 10 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Rutol	Tablet: Phenobarbital, 8.0 mg.; mannitol hexanitrate, 16 mg.; rutin, 10 mg.	Pitman-Moore.
Salisil with Phenobarbital	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.
Selbella	Tablet: Phenobarbital, ⅙ gr.; aluminum hydroxide, 5 gr.; belladonna extract, ⅓ gr.	Wyeth Laboratories.
Sed-Tens	Tablet (12 hr.): Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena	Tablet: Butabarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids 0.20 mg.).	Plough Laboratories, Inc.
Sodium nitrite with phenobarbital.	Tablet: Phenobarbital sodium, ⅓ gr.; sodium nitrite, 1 gr.; sodium bicarbonate, 2 gr.; hawthorn berries, fluid extract, ¼ minim.	Paine Drug Co.
Do	Tablet: Phenobarbital, ½ gr.; sodium nitrite, 1 gr.	Buffalo Pharmaceutical Supply Corp.

Trade name or other designation	Composition	Manufacturer or supplier
Spasticol PB	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceuticals, Inc.
Spastosed	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 227 mg.; magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.
Special Formula 711	Tablet: *d*-Amphetamine sulfate, 2.5 mg.; mephenesin, 500 mg.; salicylamide, 300 mg.	Detroit First Aid Co.
Synirin	Tablet: Pentobarbital, 8 mg.; aspirin, 324 mg	Wm.P.Poythress & Co., Inc.
TCS	Tablet: Phenobarbital 16, mg.; theobromine salicylate, 0.4 gm. calcium salicylate, 0.06 gm.	Do.
Tedral-25	Tablet: Butabarbital 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A	Tablet: Phenobarbital, 25 mg.; theophylline, 180 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tensodin	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 200 mg.	Knoll Pharmaceutical Co.
Tensophen	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P. J. Noyes Co.
Tetralute I	One bottle of buffer compound containing 4.15 gm. of sodium barbital and 0.75 gm. of barbital; other drugs and components.	Miles Laboratories, Inc.
Thedrizem	Tablet: Phenobarbital, 8 mg.; theophylline, hydrous, 100 mg.; ephedrine hydrochloride, 25 mg.	The Zemmer Co.
Theobarb	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Chemical Works.
Theobarb-R	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb Special	Tablet: Phenobarbital, 16 mg.; theobromine, 325 mg.	Do.
Theobromine and phenobarbital.	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	P. J. Noyes Co.
Theobromine-Phenobarbital	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The S. E. Massengill Co.
Do	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	The Upjohn Co.
Theobromine-Phenobarbital Compound.	Tablet: Phenobarbital, ¼ gr.; theobromine, 2½ gr.; potassium iodide, 2½ gr.; potassium bicarbonate, 2 gr.	Do.
Theobromine with Phenobarbital No. 1.	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's Inc.
Theobromine and sodium acetate with phenobarbital.	Tablet: Phenobarbital, ¼ gr.; theobromine and sodium acetate, 3 gr.	Paul B. Elder Co., Inc.
Theobromine sodium salicylate with phenobarbital.	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theocardone No. 2	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Do.
Theodide	Tablet: Phenobarbital, ¼ gr.; potassium iodide, 2½ gr.; theobromine sodium salicylate, 2½ gr.	The Vale Chemical Co., Inc.
Theoglycinate with Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with Racephedrine and Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Do.
Theoplaphen	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 gm.	The S. E. Massengill Co.
Theominal	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M	Tablet: Phenobarbital, 15 mg.; theobromine, 320 mg.	Do.
Theominal R S	Tablet: Phenobarbital, 10 mg.; theobromine, 320 mg.; alseroxylon, 1.5 mg.	Do.
Theophen	Tablet: Phenobarbital, ¼ gr.; theobromine sodium salicylate, 5 gr.; calcium carbonate, 2½ gr.	The Vale Chemical Co., Inc.
Theorate	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.
Thora-Dex No. 1	Tablet: Dextroamphetamine sulfate, 2 mg., chlorpromazine hydrochloride, 10 mg.	Smith Kline & French Laboratories.
Thora-Dex No. 2	Tablet: Dextroamphetamine sulfate, 5 mg.; chlorpromazine hydrochloride, 25 mg.	Do.
Thymodyne	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	P. J. Noyes Co.
Trocinate with Phenobarbital	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Wm. P. Poythress & Co., Inc.
Tricoloid	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	Burroughs Wellcome & Co.
Triophen	Tablet: Phenobarbital, ⅛ gr.; antropine sulfate, 1/500 gr.; magnesium trisilicate, 7 gr.	The Vale Chemical Co., Inc.
Valpin-PB	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Endo Laboratories Inc.
Vasorutin	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Buffington's, Inc.
Veralzem	Tablet: Phenobarbital, 15 mg.; veratrum viride, 50 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Veratrite	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	Neisler Laboratories, Inc.
Veritag	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	S. J. Tutag and Co.
Vertegus	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¾ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	Burt Krone Co.
Veruphen	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Viritin	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Weytabs No. 1	Tablet: *dl*-Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.; aloin, 15 mg.	The Vale Chemical Co., Inc.
Weytabs No. 2	Tablet: *dl*-Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.	Do.
Weytabs No. 3	Tablet: Phenobarbital, 15 mg.; *dl*-desoxyephedrine hydrochloride, 5 mg.; thyroid 60 mg.	Do.
W-T	Powder (4 gm.): Phenobarbital, 15 mg.; belladonna extract, 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Warren-Teed Pharmaceuticals Inc.
W-T	Tablet: Phenobarbital, 1/16 gr.; belladonna extract, 1/24 gr.; benzocaine, 1/16 gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1%.	Do.
Xaniophen	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	Pitman-Moore.
Zallogen Compound	Tablet: Phenobarbital, 8 mg.; tocamphyl, 75 mg.; homatropine methylbormide, 2.5 mg.	The S. E. Massengill Co.
Zantrate	Tablet: Cyclopentenylallylbarbituric acid, ½ gr.; ephedrine sulfate, ⅜ gr.; theophylline anhydrous, 2 gr.	The Upjohn Co.
Zem-Dab	Tablet: Butabarbital sodium, 10 mg.; dehydrocholic acid, 60 mg.; ox bile desiccated, 120 mg.; homatropine methylbromide, 2.5 mg.	The Zemmer Co.
No. 23	Tablet: Phenobarbital, ½ gr.; aminophylline, 3 gr.	Stayner Corp.
No. 35	Tablet: Phenobarbital, ⅛ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, ⅜ gr.	Do.
No. 36	Tablet: Pentabarbital sodium, ¾ gr.; ephedrine sulfate, ¾ gr.; aminophylline, 3 gr.	Do.
No. 65	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 66	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 75	Tablet: Phenobarbital, ¼ gr.; belladonna, 1/6 gr.	Bariatric Corp.
No. 88	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 89	Tablet: Phenobarbital, ½ gr.; aminophylline, 1.5 gr.	Do.
No. 111	Tablet: Phenobarbital, ½ gr.; ephedrine sulfate, ⅜ gr.	Do.
No. 136	Tablet: Phenobarbital, 20 mg.; homatropine methylbromide, 5 mg.	Do.
No. 643	Tablet: Phenobarbital, ⅛ gr.; theophylline, 2 gr.; ephedrine hydrochloride, ⅜ gr.	Do.
Rx. No. 4104	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 7½ gr.; magnesium oxide, 4 gr.; atropine sulfate, 1/300 gr.	The Zemmer Co.
Rx. No. 4105	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, 1/300 gr.	Do.
Rx. No. 4108	Capsule: Phenobarbital, ½ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 6½ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx. No. 4123	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladenna, 1/6 gr.	Do.

Trade name or other designation	Composition	Manufacturer or supplier
Rx. No. 4126	Capsule: Pentobarbital sodium, 15 mg.; extract belladonna, 10 mg.	The Zemmer Co.
Rx. No. 4143	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx. No. 4152	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Rx. No. 4155	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/600 gr.; aluminum hydroxide gel. 3¾ gr.; kaolin, 3¾ gr.	Do.
Rx. No. 4170	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 10 gr.	Do.
Rx. No. 4184	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

HEARINGS

§ 308.41 Hearings generally.

In any case where the Director shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§ 308.42–308.51, and by §§ 316.41–316.67 of this chapter.

§ 308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to § 308.44, the Director shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substance listed in schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 308.43 Waiver or modification of rules.

The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 308.44 Initiation of proceedings for rule making.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Director in the following form:

(Date)

DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS
Department of Justice,
Washington, D.C. 20537.

DEAR SIR: The undersigned_____ hereby petitions the Director to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

(Name)

(Street Address)

(City and State)

Respectfully yours,

(Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the Director shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Director need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Director within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Director shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Director shall be binding on the Director as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Director shall not control that drug or other substance.

(e) If the Director determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substance should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings (or control, transfer, or removal as the case may be).

(f) If and when the Director determines to initiate proceedings, he shall publish in the FEDERAL REGISTER general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to § 308.45. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the FEDERAL REGISTER. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Director, a summary of the subjects and issues involved.

(g) The Director may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.

§ 308.45 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rule making, shall, within 30 days after the date of publication of notice of the proposed rule making in the FEDERAL REGISTER, file with the Director a written request for a hearing in the form prescribed in § 316.42 of this chapter.

(b) Any interested person may, within the period permitted for filing a request for a hearing, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any interested person fails to file a request for a hearing, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(d) If all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing, if scheduled, and issue his final

order pursuant to § 308.48 without a hearing.

§ 308.46 Burden of proof.

At any hearing, the proponent for the issuance, amendment, or repeal of any rule or regulation shall have the burden of proof.

§ 308.47 Time and place of hearing.

The hearing will commence at the place and time designated in the notice of proposed rule making published in the FEDERAL REGISTER but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 308.48 Final order.

As soon as practicable after the presiding officer has certified the record to the Director, the Director shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.49 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Director shall issue and publish in the FEDERAL REGISTER an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.50 Control of immediate precursors.

Pursuant to section 201(e) of the Act (21 U.S.C. 811(e)), the Director may, without regard to the findings required by subsection 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)), issue and publish in the FEDERAL REGISTER an order controlling an immediate precursor. The order shall designate the schedule in which the immediate precursor is to be placed, which shall be the same schedule in which the controlled substance of which it is an immediate precursor is placed or any other schedule with a higher numerical designation. An order controlling an immediate precursor shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 308.51 Pending proceedings.

All administrative proceedings pending before the Bureau on the effective date of this Part, including the matter of listing chlordiazepoxide and its salts and diazepam as drugs subject to control under the Drug Abuse Control Amendments of 1965, shall be continued and brought to final determination in accord with the laws and regulations in effect prior to such effective date.

PART 311—REGISTRATION OF IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES

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311.51 Hearings generally.
311.52 Hearings on application for importation of schedule I and II substances.
311.53 Burden of proof.

AUTHORITY: The provisions of this Part 311 issued under secs. 1006, 1007, 1008, 501(b), 84 Stat. 1288, 1289, 1271; 21 U.S.C. 956, 957, 958, 871(b).

GENERAL INFORMATION

§ 311.01 Scope of Part 311.

Procedures governing the registration of importers and exporters of controlled substances pursuant to sections 1007 and 1008 of the Act (21 U.S.C. 957–958) are set forth generally by those sections and specifically by the sections of this part.

§ 311.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "customs territory of the United States" means the several States, the District of Columbia, and Puerto Rico.

(c) The term "export" means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

(d) The term "exporter" includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in schedules I through IV.

(e) The term "hearing" means any hearing held pursuant to this part for the granting, denial, revocation or suspension of a registration pursuant to section 1008 of the Act (21 U.S.C. 958).

(f) The term "import" means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(g) The term "importer" includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(h) The term "jurisdiction of the United States" means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(i) The terms "register" and "registration" refer only to registration required and permitted by section 1007 of the Act (21 U.S.C. 957).

(j) The term "registrant" means any person who is registered pursuant to

either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(k) Any term not defined in this section shall have the definition set forth in section 1001 of the Act (21 U.S.C. 951) or § 301.02 of this chapter.

§ 311.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

FEES FOR REGISTRATION AND REREGISTRATION

§ 311.11 Fee amounts.

(a) For each registration or reregistration to import controlled substances, the registrant shall pay a fee of $25.

(b) For each registration or reregistration to export controlled substances, the registrant shall pay a fee of $25.

§ 311.12 Time of payment; refund.

Registration and reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing. Payment should be made in the form of personal, certified or cashier's check or money order made payable to "Bureau of Narcotics and Dangerous Drugs." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

REQUIREMENTS OF REGISTRATION

§ 311.21 Persons required to register.

Every person who imports any controlled substance, or who exports any controlled substance listed in schedules I through IV, or who proposes to engage in such importation or exportation, shall obtain annually a registration unless exempted by law or pursuant to §§ 311.24–311.28. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation importing controlled substances is not required to obtain a registration.)

§ 311.22 Separate registration for independent activities.

(a) Every person who engages in more than one group of independent activities, as described in § 301.22 of this chapter shall obtain a separate registration for each group of activities as required by that section.

(b) One or more controlled substances listed in schedules II through V may be included in a single registration to engage in any independent activity. Only one basic class of controlled substance listed in schedule I, and no controlled substances listed in any other schedule, may be included in a single registration.

§ 311.23 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business at one general physical location where controlled substances are imported or exported by a person.

(b) The following locations shall be deemed not to be places where controlled substances are imported or exported:

(1) A warehouse where controlled substances are stored on behalf of a registered person, unless such substances are distributed directly from such warehouse to persons other than the registered person or persons not required to register by virtue of subsection 1007(b)(1)(B) (21 U.S.C. 957(b)(1)(B)); and

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes) nor serves as a distribution point for filling sales orders.

§ 311.24 Exemption of certain military personnel.

The requirement of registration is waived for any official of the U.S. Army, Navy, Air Force, Coast Guard, or Public Health Service who is authorized to import or export controlled substances in the course of his official duties.

§ 311.25 Exemption of law enforcement officials.

The requirement of registration is waived for any officer or employee of the Bureau, any officer of the U.S. Bureau of Customs, any officer or employee of the U.S. Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess, import or export controlled substances in the course of his official duties.

§ 311.26 Exemption for ocean vessels.

Owners of vessels described in § 301.28 of this chapter or in Article 32 of the Single Convention on Narcotic Drugs, 1961, shall not be deemed to import or export any controlled substance purchased and stored in accordance with that section.

§ 311.27 Exemption for commercial aircraft.

Air carriers operating aircraft described in § 301.29 of this chapter or in Article 32 of the Single Convention on Narcotic Drugs, 1961, shall not be deemed to import or export any controlled substance purchased and stored in accordance with that section.

§ 311.28 Exemptions for personal medical use.

(a) Any individual who has in his possession a controlled substance listed in schedules II, III, IV, or V, which he has lawfully obtained for his personal medical use, or for administration to an animal accompanying him, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), providing the following conditions are met:

(1) The controlled substance is in the original container in which it was dispensed to the individual; and

(2) The individual makes a declaration to an appropriate official of the U.S. Bureau of Customs stating:

(i) That the controlled substance is possessed for his personal use, or for an animal accompanying him; and

(ii) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name, address, and prescription number of the pharmacy or practitioner who dispensed the substance.

APPLICATIONS FOR REGISTRATION

§ 311.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a registration certificate is issued by the Director.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time any person is first registered, he will be assigned to one of 12 groups in the same manner and with the same effect as provided in § 301.31 of this chapter.

§ 311.32 Application forms; contents; signature.

(a) Any person who is required to be registered to import or export controlled substances, and who is not so registered, shall apply on BND Form 225.

(b) Any person who is registered to import or export controlled substances, shall apply for reregistration on BND Form 227.

(c) BND Form 225 may be obtained at any regional office of the Bureau or by writing to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. BND Form 227 will be mailed to each registered importer and exporter approximately 60 days before the expiration date of his registration; if any registered person does not receive such forms within 45 days before the expiration date of his registration, he must promptly give notice of such fact and request such forms by writing to the Registration Branch of the Bureau at the foregoing address.

(d) Each application for registration to import or export any basic class of controlled substance listed in schedule 1 shall include the Bureau Controlled

Substance Code Number for the basic class to be covered by such registration.

(e) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, association, trust or other entity.

§ 311.33 Filing of application; acceptance for filing; additional information; amendments to and withdrawals of applications.

Applications for registration to import or export controlled substances shall be filed, accepted for filing, supplemented, amended and withdrawn as provided in §§ 301.34–301.37 of this chapter.

ACTION ON APPLICATIONS FOR REGISTRATION; REVOCATION OR SUSPENSION OF REGISTRATION

§ 311.41 Administrative review generally.

The Director may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to Subpart A of Part 316 of this chapter. The Director shall review the application for registration and other information gathered by the Bureau regarding an applicant in order to determine whether the applicable standards of section 1008 of the Act (21 U.S.C. 958) have been met by the applicant.

§ 311.42 Application for importation of schedule I and II substances.

(a) In the case of an application for registration or reregistration to import a basic class of any controlled substance listed in schedule I or II, under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Director shall, upon the filing of such application, publish in the FEDERAL REGISTER a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the FEDERAL REGISTER, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application. If a hearing is requested, the Director shall hold a hearing on the application pursuant to § 311.51. Notice of the hearing shall be published in the FEDERAL REGISTER, and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be less than 30 days after the date of publication of such notice in the FEDERAL REGISTER. A hearing pursuant to this section may be consolidated with a hearing held pursuant to § 311.43 or § 311.44.

(b) The Director shall register an applicant to import a controlled substance listed in schedule I or II if he determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

(6) That the applicant will be permitted to import only:

(i) Such amounts of crude opium and coca leaves as the Director shall find to be necessary to provide for medical, scientific, or other legitimate purposes; or

(ii) Such amounts of any controlled substances listed in schedule I or II as the Director shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such substances are found by the Director to be inadequate; or

(iii) Such amounts of any controlled substance listed in schedule I or II as the Director shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States in any case in which the Director finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Act (21 U.S.C. 823); and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

(c) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraph (b), the Director shall consider among other factors:

(1) Compliance with the security requirements set forth in §§ 301.71–301.76 of this chapter; and

(2) Employment of security procedures to guard against in-transit losses within and without of the jurisdiction of the United States.

(d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Director shall consider:

(1) The extent of price rigidity in the light of changes in (i) raw materials and other costs and (ii) conditions of supply and demand;

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including (i) shifts in market shares and (ii) shifts in individual customers among domestic manufacturers;

(3) The existence of substantial differentials between (i) domestic prices and (ii) the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Director may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.

§ 311.43 Certificate of registration; denial of registration.

(a) The Director shall issue a Certificate of Registration (BND Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 1008 of the Act (21 U.S.C. 958). In the event the issuance of registration or reregistration is not required, the Director shall deny the application. Before denying any

application, the Director shall issue an order to show cause pursuant to § 311.47 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 311.51.

(b) The Certificate of Registration (BND Form 223) shall contain the information, and shall be displayed in the manner prescribed in § 301.44(b) of this chapter.

§ 311.44 Suspension or revocation of registration.

(a) The Director may suspend any registration pursuant to section 304(a) of the Controlled Substances Act (21 U.S.C. 824 (a)) for any period of time he determines.

(b) The Director may revoke any registration pursuant to section 304(a) of the Controlled Substances Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Director shall issue an order to show cause pursuant to § 311.47, and if requested by the registrant, shall hold a hearing pursuant to § 311.51. Notwithstanding the requirements of this section, however, the Director may suspend any registration pending a final order pursuant to § 311.45.

(d) Upon service of the order of the Director suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration and any order forms and import or export permits in his possession to the nearest office of the Bureau. The suspension or revocation of a registration shall suspend or revoke any import or export permits issued pursuant to Part 312 of this chapter. Also, upon service of the order of the Director revoking registration, the registrant shall, as instructed by the Director:

(1) Deliver all controlled substances in his possession to the nearest office of the Bureau or to authorized agents of the Bureau; or

(2) Place all controlled substances in his possession under seal as described in section 304(f) of the Controlled Substances Act (21 U.S.C. 824(f)).

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension. The registrant shall deliver the old registration and, if appropriate, any order forms and import or export permits in his possession to the nearest office of the Bureau. Also, the registrant shall, as instructed by the Director:

(1) Deliver to the nearest office of the Bureau or to authorized agents of the Bureau all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Place all of such substances under seal as described in section 304(f) of the Controlled Substances Act (21 U.S.C. 824(f)).

§ 311.45 Suspension of registration pending final order.

(a) The Director may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Director so suspends, he shall serve with the order to show cause pursuant to § 311.47 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon receipt of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration and any other forms and import or export permits in his possession to the nearest office of the Bureau. The suspension of any registration under this section shall suspend any import and export permits issued pursuant to Part 312 of this chapter.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Director or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to § 311.47 which request shall be granted by the Director, who shall fix a date for such hearing as early as reasonably possible.

§ 311.46 Extension of registration pending final order.

An applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) may have the existing registration extended and continue in effect until the date on which the Director issues his order on the application for reregistration as provided in § 301.47 of this chapter.

§ 311.47 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Bureau regarding the applicant, the Director is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Director shall serve upon the applicant an order to show cause why the registration should not be denied, as provided in § 301.48 of this chapter.

(b) If, upon information gathered by the Bureau regarding any registrant, the Director determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Director shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended, as provided in § 301.48 of this chapter.

HEARINGS

§ 311.51 Hearings generally.

(a) In any case where the Director shall hold a hearing on any registration or application thereof, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 1008 of the Act (21 U.S.C. 958), by §§ 311.52–311.53, and by the procedure for hearings pursuant to sections 303 and 304 of the Act (21 U.S.C. 823–824) set forth in §§ 301.51–301.57 of this chapter, and by the procedures for administrative hearings under the Act set forth in §§ 316.41–316.00 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

§ 311.52 Hearings on application for importation of schedule I and II substances.

A hearing on an application for registration to import a basic class of any controlled substance in schedule I or II required by § 311.42 shall be held under the same procedures prescribed in §§ 301.51–301.73 of this chapter for a hearing on an application for registration to manufacture in bulk a basic class of any controlled substance.

§ 311.53 Burden of proof.

(a) At any hearing on the granting or denial of an applicant to be registered to import or export any controlled substance in schedule I or II, the applicant shall have the burden of proving that the requirements for each registration pursuant to section 1008(a) of the Act (21 U.S.C. 958(a)) are satisfied. Any other person participating in the hearing pursuant to § 311.42 shall have the burden of proving any propositions of fact or law asserted by him in the hearings.

(b) At any other hearing for the denial of a registration, the Bureau shall have the burden of proving that the requirements for such registration pursuant to section 1008(c) of the Act (21 U.S.C. 958(c)) are not satisfied.

(c) At any hearing for the revocation or suspension of a registration, the Bureau shall have the burden of proving that the requirements for such revocation or suspension to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

PART 312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

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AUTHORITY: The provisions of this Part 312 issued under secs. 1002, 1003, 1004, 501(b), 84 Stat. 1285, 1286, 1287, 1288, 1771, 21 U.S.C. 952, 953, 954, 871(b).

§ 312.01 Scope of Part 312.

Procedures governing the importation, exportation, transshipment and in-transit shipment of controlled substances pursuant to sections 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

§ 312.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) Any term not defined in this section shall have the definition set forth in sections 1001 and 102 of the Act (21 U.S.C. 951 and 802) and § 311.02 of this chapter.

IMPORTATION OF CONTROLLED SUBSTANCES

§ 312.11 Requirement of authorization to import.

(a) No person shall import or cause to be imported any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedules III, IV, or V unless and until such person is registered under the Act (or exempt from registration) and the Director has issued him a permit to do so pursuant to § 312.13.

(b) No person shall import or cause to be imported any nonnarcotic controlled substances listed in schedules III, IV, or V unless and until such person is registered under the Act (or exempt from registration) and he has filed an import declaration to do so with the Director at least 15 days prior to importation, pursuant to § 312.18.

(c) When an import permit or declaration is required, a separate permit or declaration must be obtained for each consignment of controlled substances to be imported.

§ 312.12 Application for import permit.

(a) An application for a permit to import controlled substances shall be made on BND Form 85. BND Form 85 may be obtained from, and shall be filed with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. Each application shall show the date of execution, the registration number of the importer, and the name and detailed description of each of the controlled substances desired to be imported, the net quantity of each, the anhydrous alkaloid content in any narcotic controlled substance to be imported, if known, the number and size of packages or containers, the name and quantity of the controlled substance contained in any preparation, and the quantity of any solids being given in kilograms or parts thereof. The application shall also include the following:

(1) The name, address, and business of the consignor, if known at the time application is submitted, but if unknown at that time, the fact should be indicated and the name and address afterwards furnished to the Director as soon as ascertained by the importer;

(2) The foreign port of exportation (i.e.), the place where the article will begin its journey of exportation to the United States);

(3) The port of entry into the United States;

(4) The latest date said shipment will leave said foreign port;

(5) The stock on hand of the controlled substance desired to be imported;

(6) The name of the importing carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, imports of controlled substances in schedules I or II and narcotic drugs in schedules III, IV, or V by mail being prohibited);

(7) The total tentative allotment to the importer of such controlled substance for the current calendar year;

(8) The total number of kilograms of said allotment for which permits have previously been issued and the total quantity of controlled substance actually imported during the current year to date.

(b) If desired, alternative foreign ports of exportation within the same country may be indicated upon the application (e.g., (1) Calcutta, (2) Bombay). If a formal permit is issued pursuant to such application, it will bear the names of the two ports in the order given in the application and will authorize shipment from either port. Alternate ports in different countries will not be authorized in the same permit.

§ 312.13 Issuance of import permit.

(a) The Director may authorize importation of any controlled substance listed in schedule I or II or any narcotic drug in listed schedule III, IV, or V if he finds:

(1) That the substance is crude opium or coca leaves in such quantity as he finds necessary to provide for medical, scientific, or other legitimate purposes;

(2) That the substance is necessary to provide for medical and scientific needs or other legitimate needs of the United States during an emergency where domestic supplies of such substance or drug are found to be inadequate, or in any case in which the Director finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Controlled Substances Act (21 U.S.C. 823); or

(3) That the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(b) If, after careful consideration of the application, it is found that approval cannot be given, such fact and the reasons therefor will be communicated to the applicant by the Director. If additional information is required, or other action is necessary to correct any mistake or irregularity in the application or accompanying documents, opportunity will be afforded the prospective importer by the Director to furnish such additional information or to correct such mistake or irregularity before the application is finally approved.

(c) Each import permit shall be issued in sextuplet and serially numbered, with all six copies bearing the same serial number and being designated "original" (Copy 1), "duplicate" (Copy 2), etc., respectively. All copies of import permits shall bear the signature of the Director or his delegate, and facsimiles of signatures shall not be used. No permit shall be altered or changed by any person after being signed by the Director or his delegate and any change or alteration upon the face of any permit, after it shall have been signed by the Director or his delegate shall render it void and of no effect. Permits are not transferable. Each copy of the permit shall have printed or stamped thereon the disposition to be made thereof. Each permit shall be dated and shall certify that the importer named therein is thereby permitted as a registrant under the Act, to import, through the port named, one shipment of not to exceed the specified quantity of the named controlled substances, shipment to be made before a specified date. Not more than one shipment shall be made on a single import permit. The permit shall state that the Director is satisfied that the consignment proposed to be imported is required for legitimate purposes.

§ 312.14 **Distribution of copies of import permit.**

Copies of the import permit shall be distributed and serve purposes as follows:

(a) The original and quintuplet copies (Copy 1 and Copy 5) shall be transmitted by the Bureau to the importer, who shall retain the quintuplet copy (Copy 5) on file as his record of authority for the importation, and shall transmit the original copy (Copy 1) to the foreign exporter. The foreign exporter will submit the original copy (Copy 1) to the proper governmental authority in the exporting country, if required, as a prerequisite to the issuance of an export authorization. This copy of the permit will accompany the shipment. Upon arrival of the imported merchandise, the District Director of the U.S. Bureau of Customs, at the port of entry will, after appraising the merchandise, forward the original copy (Copy 1) to the Distribution Audit Branch with a report on the reverse side of such copy, showing the name of the port of importation, date prepared, name and net quantity of each substance, and report of analysis of the merchandise entered.

(b) The duplicate copy (Copy 2) shall be forwarded by the Bureau to the proper governmental authorities of the exporting country.

(c) The triplicate copy (Copy 3) shall be forwarded by the Bureau to the District Director of the U.S. Bureau of Customs at the U.S. port of entry, which shall be the customs port of destination in the case of shipments transported under immediate transportation entries, in order that the District Director may compare it with the original copy (Copy 1) and the bill of lading upon arrival of the merchandise. If a discrepancy is noted between corresponding items upon different copies of a permit bearing the same serial number when compared by the District Director, he shall refuse to permit entry of the merchandise until the facts are communicated to the Bureau and further instructions are received.

(d) The triplicate copy (Copy 3) and sextuplet copy (Copy 6) shall be retained by the Bureau.

§ 312.15 **Shipments in greater or less amount than authorized.**

(a) If the shipment made under an import permit is greater than the maximum amount authorized to be imported under the permit, as determined at the weighing by the District Director of the U.S. Bureau of Customs, such difference shall be seized subject to forfeiture, pending an explanation; except that shipments of substances exceeding the maximum authorized amount by less than 1 percent may be released to the importer upon the filing by him of an amended import permit. If the substance is included in schedule I, it will be summarily forfeited to the Government.

(b) If the shipment made under the permit is less than the maximum amount authorized to be imported under the permit as determined at the weighing by the District Director of the U.S. Bureau of Customs, such difference, when ascertained by the Bureau, shall be recredited to the tentative allotment against which the quantity covered by the permit was charged, and the balance of any such tentative allotment with any such recredits will remain available to the importer to whom made (unless previously revoked in whole or in part), for importations pursuant to any permit or permits as are requested and issued during the remainder of the calendar year to which the allotment is applicable. No permit shall be issued for importation of a quantity of controlled substances as a charge against the tentative allotment for a given calendar year, after the close of such calendar year, unless the Director of the Bureau decides to make an exception for good cause shown.

§ 312.16 **Cancellation of permit; expiration date.**

(a) A permit may be canceled after being issued, at the request of the importer, provided no shipment has been made thereunder. In the event that a permit is lost, the Director may, upon the production by the importer of satisfactory proof, by affidavit or otherwise, issue a duplicate permit. Nothing in this part shall affect the right, hereby reserved by the Director, to cancel a permit at any time for proper cause.

(b) An import permit shall not be valid after the date specified therein, and in no event shall the date be subsequent to 6 months after the date the permit is issued. Any unused import permit shall be returned for cancellation by the registrant to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

§ 312.17 **Special report from importers.**

Whenever requested by the Director, importers shall render to him not later than 30 days after receipt of the request therefor a statement under oath of the stocks of controlled substances on hand as of the date specified by the Director in his request, and, if desired by the Director, an estimate of the probable requirements for legitimate uses of the importer for any subsequent period that may be designated by the Director. In lieu of any special statement that may be considered necessary, the Director may accept the figures given upon the reports subsequent by said importer under Part 304 of this chapter.

§ 312.18 **Contents of import declaration.**

(a) Any nonnarcotic substance listed in schedule III, IV, or V may be imported if that substance is needed for medical, scientific or other legitimate uses in the United States, and will be imported pursuant to controlled substances import declaration.

(b) A registrant desiring to import any nonnarcotic controlled substance in schedules III, IV, or V must furnish a controlled substances import declaration on BND Form 236 to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005, not later than 15 calendar days prior to the proposed date of importation and distribute four copies of same as hereinafter directed in § 312.19.

(c) BND Form 236 must be executed in quintuplicate and will include the following information:

(1) The name, address, and registration number of the importer; and the name and address and registration number of the import broker, if any; and

(2) A complete description of the controlled substances to be imported, including name, quantity, and dosage units; and

(3) The proposed import date, the foreign port of exportation to the United States, the port of entry, and the name, address, and registration number of the recipient in the United States; and

(4) The name and address of the consignor in the foreign country of exportation, and any registration or license numbers if the consignor is required to have such numbers either by the country of exportation or under U.S. law.

(d) Notwithstanding the time limitations included in paragraph (a) of this section, a registrant may obtain a special waiver of these time limitations in emergency or unusual instances, provided that a specific confirmation is received from the Director or his delegate advising the registrant to proceed pursuant to the special waiver.

§ 312.19 **Distribution of import declaration.**

The required five copies of the controlled substances import declaration will be distributed as follows:

(a) Copy 1, Copy 2, and Copy 3 shall be transmitted to the foreign shipper. The foreign shipper will submit Copy 1 to the proper governmental authority in the foreign country, if required as a prerequisite to export authorization. Copy 1 will then accompany the shipment to its destination, and shall be retained on file by the importer. Copy 2 shall be detached and retained by the appropriate customs official of the foreign country. Copy 3 shall be removed by the District Director of the U.S. Bureau of Customs at the port of entry, who shall sign and date the certification of customs on Copy 3, noting any changes from the entries made by the importer, and shall then forward that copy to the Registration Branch of the Bureau.

(b) Copy 4 shall be forwarded, within the time limit required in § 312.18, directly to the Distribution Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washingthon, D.C. 20005, at least 15 days prior to the proposed date of importation.

(c) Copy 5 shall be retained by the importer on file as his record of authority for the importation.

EXPORTATION OF CONTROLLED SUBSTANCES

§ 312.21 Requirement of authorization to export.

(a) No person shall in any manner export or cause to be exported from the United States any controlled substance listed in schedule I or II, and any narcotic drug listed in schedule III or IV, unless and until such person is registered under the Act (or exempted from registration) and the Director has issued him a permit to do so pursuant to § 312.23.

(b) No person shall in any manner export or cause to be exported from the United States any nonnarcotic controlled substance listed in schedule III or IV or any controlled substance listed in schedule V, unless and until such person is registered under the Act (or exempted from registration) and he has furnished a special controlled substance export invoice as provided by section 1003(e) of the Act (21 U.S.C. 953(e)) to the Director pursuant to § 312.26.

(c) A separate authorization request is obtained for each consignment of such controlled substances to be exported.

§ 312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on BND Form 161 which may be obtained from, and shall be filed with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. Each application shall show the exporter's name, address, and registration number, the name and detailed description of each controlled substance desired to be exported, the net quantity thereof, the number and size of packages or containers, the name and quantity of the controlled substance contained in any preparation, and the quantity of any solids being given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971, and that, to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical and scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country. In the case of exportation of bulk coca leaf alkaloid, the affidavit may state that to the best of knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

(b) There shall also be submitted with the application any import license or permit (and a translation thereof if in a foreign language) or a certified copy of any such license or permit issued by competent authorities in the country of destination, or other documentary evidence deemed adequate by the Director, showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical or scientific use within the country of destination, that it will not be reexported from such country, and that there is an actual need for the controlled substance for medical or scientific use within such country. (In the case of exportation of bulk coca leaf alkaloid, the submitted evidence need only show the material outlined in paragraph (a) of this section for such exportations.)

§ 312.23 Issuance of export permit.

(a) The Director may authorize exportation of any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedule III or IV if he finds that such exportation is permitted by subsections 1003 (a), (b), (c), or (d) of the Act (21 U.S.C. 953 (a), (b), (c) or (d)).

(b) If after careful consideration of the application it is found that approval cannot be given, such fact and the reasons therefor will be communicated to the applicant by the Director. If additional information is required, or other action is necessary to correct any mistake or irregularity in the application or accompanying documents, opportunity will be afforded the prospective exporter by the Director to furnish such additional information or to correct such mistake or irregularity before the application is finally disapproved.

(c) Each export permit shall be issued in septuplet and serially numbered, with all seven copies bearing the same serial number and being designated "original" (Copy 1), "duplicate" (Copy 2), etc., respectively. Each export permit shall be predicated upon a separate import certificate or other documentary evidence, and not more than one shipment shall be made thereon. Export permits are not transferable.

(d) No export permit shall be issued for the exportation of any narcotic drug to any country when the Director has information to show that the estimates submitted with respect to that country for the current period, under the Narcotics Limitation Convention of 1931, or the Single Convention on Narcotic Drugs of 1961, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear, through subsequent advice received from the International Narcotic Control Board of the United Nations that the estimates of the country of destination have been adjusted to permit further importation of the narcotic drug, an export permit may then be issued if otherwise permissible.

§ 312.24 Distribution of copies of export permit.

Copies of the export permit shall be distributed and serve purposes as follows:

(a) The original, duplicate, and triplicate copies (Copy 1, Copy 2, and Copy 3) shall be transmitted by the Bureau to the exporter who will retain the triplicate copy (Copy 3) as his record of authority for the exportation. The exporter shall present to the District Director of the U.S. Bureau of Customs, at the port of export and at the time of shipment, the original and duplicate copies (Copy 1 and Copy 2). After endorsing the port of export on the reverse side of the original and duplicate copies (Copy 1 and Copy 2) the District Director shall forward the endorsed original copy (Copy 1) with the shipment, and return the endorsed duplicate copy (Copy 2) to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) The quadruplet copy (Copy 4) shall be forwarded by the Bureau to the District Director of the U.S. Bureau of Customs at the port of export for comparison with the original copy (Copy 1) and for retention for the customs record.

(c) The quintuplet copy (Copy 5) shall be forwarded by the Bureau to the officer in the country of destination who issued the import certificate, or other documentary evidence upon which the export permit is founded.

(d) The sextuplet and septuplet copies (Copy 6 and Copy 7) shall be retained by the Bureau.

§ 312.25 Expiration date.

An export permit shall not be valid after the date specified therein, which date shall conform to the expiration date specified in the supporting import certificate or other documentary evidence upon which the export permit is founded, but in no event shall the date be subsequent to 6 months after the date the permit is issued. Any unused export permit shall be returned by the permittee to the Distribution Audit Branch for cancellation.

§ 312.26 Records required of exporter.

The exporter shall keep a record of any serial numbers that might appear on packages of narcotic drugs in quantities of one ounce or more in such a manner as will identify the foreign consignee, along with Copy 3 of the export permit.

§ 312.27 Contents of special controlled substances invoice.

(a) A registrant desiring to export any nonnarcotic controlled substance listed in schedule III or IV or any controlled substance listed in schedule V

must furnish a special controlled substances export invoice on BND Form 236 to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005, not less than 15 calendar days prior to the proposed date of exportation, and distribute four copies of same as hereinafter directed in § 312.27.

(b) This invoice must be executed by the exporter in quintuplicate and include the following information.

(1) The name, address, and registration number of the exporter; and the name, address and registration number of the exporter broker, if any; and

(2) A complete description of the controlled substances to be exported, including the name, quantity and dosage units; and

(3) The proposed export date, the port of exportation, the foreign port of entry, the carriers and shippers involved, method of shipment, the name of the vessel if applicable, and the name, address, and registration number, if any, of any forwarding agent utilized; and

(4) The name and address of the consignee in the country of destination, and any registration or license numbers if the consignee is required to have such numbers either by the country of destination or under United States law. In addition, documentation must be provided to show that such consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances.

(c) Notwithstanding the time limitations included in paragraph (a) of this section, a registrant may obtain a special waiver of these time limitations in emergency or unusual instances; provided that a specific confirmation is received from the Director or his delegate advising the registrant to proceed pursuant to the special waiver.

§ 312.28 Distribution of special controlled substances invoice.

The required five copies of the special controlled substances export invoice, BND Form 236, will be distributed as follows:

(a) Copy 1 shall accompany the shipment and remain with the shipment to its destination.

(b) Copy 2 shall accompany the shipment and will be detached and retained by appropriate customs officials at the foreign country of destination.

(c) Copy 3 shall accompany the shipment and will be detached by the District Director of the U.S. Bureau of Customs at the port of exportation, who shall sign and date the certification of customs on such Copy 3, noting any changes from the entries made by the exporter, and shall then promtly forward Copy 3 to the Registration Branch of the Bureau.

(d) Copy 4 shall be forwarded, within the time limit required in § 312.27, directly to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. These must be attached to this copy documentation (including registration numbers if required) that such consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances.

(e) Copy 5 shall be retained by the exporter on file as his record of authority for the exportation.

§ 312.29 Domestic release prohibited.

An exporter or a forwarding agent acting for an exporter must either deliver the controlled substances to the port or border, or deliver the controlled substances to a bonded carrier approved by the consignor for delivery to the port or border, and may not, under any other circumstances, release a shipment of controlled substances to anyone, including the foreign consignee or his agent, within the United States.

Transshipment and In-Transit Shipment of Controlled Substances

§ 312.31 Schedule I: Application for prior written approval.

(a) A controlled substance listed in schedule I may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that:

(1) The controlled substance is necessary for scientific, medical, or other legitimate purposes in the country of destination, and

(2) Prior written approval has been granted by the Director.

(b) An application for prior written approval must be submited to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, at least 30 days, or in the case of an emergency as soon as practicable, prior to the expected date of importation, transfer or transshipment. Each application shall contain the following:

(1) The date of execution;

(2) The identification and description of the controlled substance;

(3) The net quantity thereof;

(4) The number and size of the controlled substance containers;

(5) The name, address, and business of the foreign exporter;

(6) The foreign port of exportation;

(7) The approximate date of exportation;

(8) The identification of the exporting carrier;

(9) The name, address and business of the importer, transferor, or transshipper;

(10) The registration number, if any, of the importer, transferor or transshipper;

(11) The U.S. port of entry;

(12) The approximate date of entry;

(13) The name, address and business of the consignee at the foreign port of entry;

(14) The shipping route from the U.S. port of exportation to the foreign port of entry;

(15) The approximate date of receipt by the consignee at the foreign port of entry; and

(16) The signature of the importer, transferor or transhipper, or his agent accompanied by the agent's title.

(c) An application shall be accompanied by an export license, permit, or a certified copy of the export license, permit, or other authorization, issued by a competent authority of the country of origin (or other documentary evidence deemed adequate by the Director).

(d) An application shall be accompanied by an import license or permit or a certified copy of such license or permit issued by a competent authority of the country of destination (or other documentary evidence deemed adequate by the Director), indicating that the controlled subtance:

(1) Is to be applied exclusively to scientific, medical or other legitimate uses within the country of destination;

(2) Will not be exported from such country; and

(3) Is needed therein because there is an actual shortage thereof and a demand therefor for scientific, medical or other legitimate uses within such country.

(e) Verification by an American consular officer of the signatures on a foreign import license or permit shall be required, if such license or permit does not bear the seal of the authority signing them.

(f) The Director shall, within 21 days from the date of receipt of the application, review it and rule thereon, either granting or denying the application. Prior to a denial, however, the Director shall notify the applicant that approval cannot be granted, stating the reasons therefor. The applicant shall be accorded an opportunity to amend the application, with the Director either granting or denying the amended application within 7 days of its receipt.

(g) If the Director does not grant or deny the application within 21 days of its receipt, or in the case of an amended application, within 7 days of its receipt, it shall be deemed approval of the application, and the applicant may proceed.

§ 312.32 Schedules II, III, IV: Advance Notice.

(a) A controlled substance listed in schedules II, III, or IV may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that written notice is submitted to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005, at least 15 days prior to the expected date of importation, transfer or transshipment.

(b) Each advance notice shall contain those items required by § 312.31 (b) and (c).

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316.80 Time for filing petitions.
316.81 Handling of petitions.

Subpart A—Administrative Inspections

AUTHORITY: The provisions of this Subpart A of Part 316 issued under secs. 302(f), 501(b), 510, 1008(d), 1015, 84 Stat. 1253, 1271, 1274, 1275, 1276, 1289, 1291; 21 U.S.C. 822(f), 871(b), 880, 958(d), 965.

§ 316.01 Scope of Subpart A.

Procedures regarding administrative inspections and warrants pursuant to sections 302(f), 510, 1008(d), and 1015 of the Act (21 U.S.C. 822(f), 880, 958(d), and 965) are governed generally by those sections and specifically by the sections of this Subpart.

§ 316.02 Definitions.

As used in this Subpart, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "Bureau" means the Bureau of Narcotics and Dangerous Drugs.

(c) The term "controlled premises" means—(1) Places where original or other records or documents required under the Act are kept or required to be kept, and

(2) Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.

(d) The term "Director" means the Director of the Bureau. The Director has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(e) The term "inspector" means an officer or employee of the Bureau authorized by the Director to make inspections under the Act.

(f) The term "register" and "registration" refer to registration required and permitted by sections 303 and 1008 of the Act (21 U.S.C. 823 and 958).

(g) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951).

§ 316.03 Authority to make inspections.

In carrying out his functions under the Act, the Director, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and the regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to Part 304 of this chapter, order form records required to be kept pursuant to Part 305 of this chapter, prescription and distribution records required to be kept pursuant to Part 306 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;

(b) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances on-hand at the premises;

(d) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on BND Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so why); and

(f) Except as provided in § 316.04, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

§ 316.04 Exclusion from inspection.

(a) Unless the owner, operator or agent in charge of the controlled premises so consents in writing, no inspection authorized by these regulations shall extend to:

(1) Financial data;

(2) Sales data other than shipping data; or

(3) Pricing data.

§ 316.05 Entry.

An inspection shall be carried out by an inspector. Any such inspector, upon (a) Stating his purpose and (b) Presenting to the owner, operator or agent in charge of the premises to be inspected (1) Appropriate credentials, and (2) Written notice of his inspection authority under § 314.06 of this chapter, and (c) Receiving informed consent under § 316.08 or through the use of administrative warrant issued under §§ 216.09–316.14, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

§ 316.06 Notice of inspection.

The notice of inspection (BND Form 82) shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to section 510 of the Act (21 U.S.C. 880);

(f) A reproduction of the pertinent parts of section 510 of the Act; and

(g) The signature of the inspector.

§ 316.07 Requirement for administrative inspection warrant; exceptions.

In all cases where an inspection is contemplated, an administrative inspection warrant is required pursuant to section 510 of the Act (21 U.S.C. 880), except that such warrant shall not be required for establishments applying for initial registration under the Act, for the inspection of books and records pursuant to an administrative subpoena issued in accordance with section 506 of the Act (21 U.S.C. 876) nor for entries in administrative inspections (including seizures of property):

(a) With the consent of the owner, operator, or agent in charge of the controlled premises as set forth in § 316.08;

(b) In situations presenting imminent danger to health or safety;

(c) In situations involving inspection of conveyances where there is reasonable cause to obtain a warrant;

(d) In any other exceptional or emergency circumstance or time or opportunity to apply for a warrant is lacking; or

(e) In any other situations where a warrant is not constitutionally required.

§ 316.08 Consent to inspection.

(a) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected.

(b) Wherever possible, informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected and witnessed by two persons. The written consent shall contain the following information:

(1) That he (the owner, operator, or agent in charge of the premises) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;

(2) Of his right to refuse to consent to such an inspection;

(3) Of the possibility that anything of an incriminating nature which may be found may be seized and used against him in a criminal prosecution;

(4) That he has been presented with a notice of inspection as set forth in § 316.06;

(5) That the consent is given by him is voluntary and without threats of any kind; and

(6) That he may withdraw his consent at any time during the course of inspection.

(c) The written consent shall be produced in duplicate and be distributed as follows:

(1) The original will be retained by the inspector; and

(2) The duplicate will be given to the person inspected.

§ 316.09 Application for administrative inspection warrant.

(a) An administrative inspection warrant application shall be submitted to any judge of the United States or of a State court of record, or any United States magistrate which shall contain the following information:

(1) The name and address of the controlled premises to be inspected;

(2) A statement of statutory authority for the administrative inspection warrant, and that the fact that the particular inspection in question is designed to insure compliance with the Controlled Substances Act or the Controlled Substances Import and Export Act and the regulations promulgated under those Acts;

(3) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances;

(4) A statement that the establishment either:

(i) has not been previously inspected, or

(ii) was last inspected on a particular date.

(b) The application shall be submitted under oath to an appropriate judge or magistrate.

§ 316.10 Administrative probable cause.

If the judge or magistrate is satisfied that "administrative probable cause," as defined in section 510(d)(1) of the Act (21 U.S.C. 880(d)(1)) exists, he shall issue an administrative warrant. Administrative probable cause shall not mean criminal probable cause as defined by Federal statute or case law.

§ 316.11 Execution of Warrants.

An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of, section 510(d)(3) of the Act (21 U.S.C. 880(d)(3)). The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

§ 316.12 Refusal to allow inspection with an administrative warrant.

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of section 402(a)(6) of the Act (21 U.S.C. (a)(6)). If he persists and the circumstances warrant, he shall be arrested and the inspection shall commence or continue.

§ 316.13 Frequency of administrative inspections.

Except where circumstances otherwise dictate, it is the intent of the Bureau to inspect all manufacturers of controlled substances listed in schedules I and II and distributors of controlled substances listed in schedule I once each year; and to inspect all distributors of controlled substances listed in schedules II through V and manufacturers of controlled substances listed in schedules III through V once every 3 years.

Subpart B—Protection of Researchers and Research Subjects

AUTHORITY: The provisions of this Subpart B of Part 316 issued under secs. 501(b), 502(c), 502(d), 84 Stat. 1271; 21 U.S.C. 871(b), 872(c), 872(d).

§ 316.21 Confidentiality of research subjects.

(a) Any person registered to conduct research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), who intends to maintain the confidentiality of those persons who are the subjects of such research, shall, upon registration or within a reasonable time thereafter, submit to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, a separate request for each research project involving controlled substances, which shall contain the following:

(1) The researcher's registration number for that project;

(2) The location of the research project;

(3) A general description of the research or a copy of the research protocol;

(4) A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and

(5) The reasons supporting the request.

(b) Within 30 days from the date of receipt of the request, the Director shall issue a letter, either granting confidentiality, requesting additional information, or denying confidentiality, in which case the reasons for the denial shall be included. A grant of confidentiality shall be limited solely to the specific research project indicated in the request.

(c) Within 30 days after the date of completion of the research project, the researcher shall so notify the Director.

§ 316.22 Exemption from prosecution for researcher.

(a) Upon registration of a practitioner to engage in research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), the Director of the Bureau of Narcotics and Dangerous Drugs, on his own motion or upon request in writing from the Secretary or from the practitioner, shall exempt the registrant when acting within the scope of his registration, from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301).

(b) The exemption shall consist of a letter issued by the Director, which shall include:

(1) The researcher's name and address;

(2) The researcher's registration number from the research project;

(3) The location of the research project;

(4) A concise statement of the scope of the researcher's registration; and

(5) The limits of the exemption.

(c) The exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his renewal of registration is denied. Within 30 days of the date of completion of the research project, the researcher shall so notify the Director. The Director shall issue another letter including the information required in paragraph (b) of this section and stating the date on which the period of exemption concluded; upon receipt of this letter, the researcher shall return the original letter of exemption.

Subpart C—Enforcement Proceedings

AUTHORITY: The provisions of this Subpart C of Part 316 issued under secs. 501(b), 513, 84 Stat. 1271, 1278, 21 U.S.C. 871(b), 883.

§ 316.31 Authority for enforcement proceeding.

A hearing may be ordered or granted by any Regional Director of the Bureau of Narcotics and Dangerous Drugs, at his discretion, to permit any person against whom criminal and/or civil action is contemplated under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951) an opportunity to present his views and his proposals for bringing his alleged violations into compliance with the law. Such hearing will also permit him to show cause why prosecution should not be instituted, or to present his views on the contemplated proceeding.

§ 316.32 Notice of proceeding; time and place.

Appropriate notice designating the time and place for the hearing shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given, the time or place of the hearing, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Regional Director who issued the notice.

§ 316.33 Conduct of proceeding.

Presentation of views at a hearing under this Subpart shall be private and informal. The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his authorized representative.

§ 316.34 Records of proceeding.

A formal record, either verbatim or summarized, of the hearing may be made at the request of either the Regional Director or the person for whom the hearing is being conducted. If such record is to be made at the request of the Regional Director, the person attending the hearing will be so advised prior to the start of the hearing.

Subpart D—Administrative Hearings

AUTHORITY: The provisions of this Subpart D issued under secs. 201, 301, 501(b), 505, 84 Stat. 1245, 1246, 1247, 1253, 1271, 1272; 21 U.S.C. 811, 821, 871(b), 875.

§ 316.41 Scope of Subpart D.

Procedures in any administrative hearing held under the Act are governed generally by the rule making and/or adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by the procedures set forth in this Subpart, except where more specific regulations (set forth in §§ 301.51–301.57, §§ 303.41–303.47, or §§ 308.41–308.51) apply.

§ 316.42 Definitions.

As used in this Subpart, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "Director" means the Director of the Bureau. The Director has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(c) The term "hearing" means any hearing held pursuant to the Act.

(d) The term "Hearing Clerk" means the hearing clerk of the Bureau.

(e) The term "person" includes an individual, corporation, government or governmental subdivision or agency, business trust, partnership, association or other legal entity.

(f) The term "presiding officer" means a hearing examiner qualified and appointed as provided in the Administrative Procedure Act (5 U.S.C. 556).

(g) The term "proceeding" means all actions involving a hearing, commencing with the publication by the Director of the notice of proposed rule making or the issuance of an order to show cause.

(h) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and in § 301.02 of this chapter.

§ 316.43 Information; special instructions.

Information regarding procedure under these rules and instructions supplementing these rules in special instances will be furnished by the Hearing Clerk upon request.

§ 316.44 Waiver or modification of rules.

The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this subpart by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 316.45 Filings; address; hours.

Documents required or permitted to be filed in, and correspondence relating to, hearings governed by the regulations in this chapter shall be filed with the Hearing Clerk, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. This office is open Monday through Friday from 9 a.m. to 5:30 p.m. eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time, except on national legal holidays. Documents shall be dated and deemed filed upon receipt by the Hearing Clerk.

§ 316.46 Inspection of record.

(a) The record bearing on any proceeding, except for material described in subsection (b) of this section, shall be available for inspection and copying by any person entitled to participate in such proceeding, during office hours in the office of the Hearing Clerk, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) The following material shall not be available for inspection as part of the record:

(1) A research protocol filed with an application for registration to conduct research with controlled substances listed in schedule I, pursuant to § 301.32(a)(3) of this chapter, if the applicant requests that the protocol be kept confidential;

(2) An outline of a production or manufacturing process filed with an application for registration to manufacture a new narcotic controlled substance, pursuant to § 301.33 of this chapter, if the applicant requests that the outline be kept confidential;

(3) Any confidential or trade secret information disclosed in conjunction with an application for registration, or in reports filed while registered, or acquired in the course of an investigation, entitled to protection under subsection 402(a)(8) of the Act (21 U.S.C. 842(a)(8)) or any other law restricting public disclosure of information; and

(4) Any material contained in any investigatory report, memorandum, or file, or case report compiled by the Bureau.

§ 316.47 Request for hearing.

Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing in the following form:

---------- (Date)

DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS,
Department of Justice,
Washington, D.C. 20537.

DEAR SIR: The undersigned ---------- (Name of ---------- hereby requests a hearing in person)

the matter of: ----------

(Identification of the proceeding)
(A) (State with particularity the interest of the person in the proceeding.)
(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)
(C) (State briefly the position of the person with regard to the particular objections or issues.)
All notices to be sent pursuant to the proceeding should be addressed to:

(Name)

(Street address)

(City and State)

Respectfully yours,

(Signature of person)

§ 316.48 Notice of appearance.

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he has not filed a request for hearing, file within the time specified in the notice of proposed rule making, a written notice of appearance in the following form:

(Date)

DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS,
Department of Justice,
Washington, D.C.

DEAR SIR: Please take notice that ---------- will appear in the matter of: ----------
(Identification of the proceeding)
(A) (State with particularity the interest of the person in the proceeding.)
(B) (State with particularity the objections or issues, if any, concerning which the interested person desires to be heard).
(C) (State briefly the position of the person with regard to the particular objections or issues.)
All notices to be sent pursuant to this appearance should be addressed to:

(Name)

(Street address)

(City and State)

Respectfully yours,

(Signature of person)

§ 316.49 Waiver of hearing.

Any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

§ 316.50 Appearance; representation; authorization.

Any person entitled to appear in a hearing may appear in person or by or with a representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration. A representative must either be an employee of the person or an attorney at law who is a member of the bar, in good standing, of any State, territory, or the District of Columbia, and admitted to practice before the highest court of that jurisdiction. Any representative may be required by the Director or the presiding officer to present a notarized power of attorney showing his authority to act in such representative capacity and/or an affidavit or certificate of admission to practice.

§ 316.51 Conduct of hearing and parties; ex parte communications.

(a) Hearings shall be conducted in an informal but orderly manner in accordance with law and the directions of the presiding officer.

(b) Participants in any hearing and their representatives, whether or not members of the bar, shall conduct themselves in accordance with judicial standards of practice and ethics and the directions of the presiding officer. Refusal to comply with this section shall constitute grounds for immediate exclusion from any hearing.

(c) If any official of the Bureau is contacted by any individual in private or public life concerning any substantive matter which is the subject of any hearing, at any time after the date on which the proceedings commence, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file. The presiding officer and employees of the Bureau shall comply with the requirements of 5 U.S.C. 554(d) regarding ex parte communications and participation in any hearing.

§ 316.52 Presiding officer.

A presiding officer, designated by the Director, shall preside over all hearings. The functions of the presiding officer shall commence upon his designation and terminate upon the certification of the record to the Director. The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

(a) Arrange and change the date, time, and place of hearings (other than the time and place prescribed in § 301.60) and prehearing conferences and issue notice thereof.

(b) Hold conferences to settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing.

(c) Require parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.

(d) Examine witnesses and direct witnesses to testify.

(e) Receive, rule on, exclude, or limit evidence.

(f) Rule on procedural items pending before him.

(g) Take any action permitted to the presiding officer as authorized by this Part or by the provisions of the Administrative Procedure Act (5 U.S.C. 551–559).

§ 316.53 Time and place of hearing.

The hearing will commence at the place and time designated in the notice of hearing published in the FEDERAL REGISTER but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 316.54 Prehearing conference.

The presiding officer on his own motion, or on the motion of any party for good cause shown, may direct all parties to appear at a specified time and place for a conference for:

(a) The simplification of the issues.
(b) The possibility of obtaining stipulations, admission of facts, and documents.
(c) The possibility of limiting the number of expert witnesses.
(d) The identification and, if practicable, the scheduling of all witnesses to be called.
(e) The advance submission at the prehearing conference of all documentary evidence and affidavits to be marked for identification.
(f) Such other matters as may aid in the expeditious disposition of the hearing.

§ 316.55 Prehearing ruling.

The presiding officer may have the prehearing conference reported verbatim and shall make a ruling reciting the action taken at the conference, the agreements made by the parties, the schedule of witnesses, and a statement of the issues for hearing. Such ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.

§ 316.56 Burden of proof.

At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.

§ 316.57 Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference.

All documentary evidence and affidavits not submitted and all witnesses not identified at the prehearing conference shall be submitted or identified to the presiding officer as soon as possible, with a showing that the offering party had good cause for failing to so submit or identify at the prehearing conference. If the presiding officer determines that good cause does exist, the documents or affidavits shall be submitted or witnesses identified to all parties sufficiently in advance of the offer of such documents or affidavits or witnesses at the hearing to avoid prejudice or surprise to the other parties. If the presiding officer determines that good

cause does not exist, he may refuse to admit as evidence such documents or affidavits or the testimony of such witnesses.

§ 316.58 Summary of testimony; affidavits.

(a) The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing. Witnesses will not be permitted to read summaries of their testimony into the record and all witnesses shall be available for cross-examination. Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) Affidavits submitted at the prehearing conference or pursuant to § 301.63 with good cause may be examined by all parties and opposing affidavits may be submitted to the presiding officer within a period of time fixed by him. Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to statements made therein.

§ 316.59 Submission and receipt of evidence.

(a) The presiding officer shall admit only evidence that is competent, relevant, material and not unduly repetitious.

(b) Opinion testimony shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(c) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer, except that a party will be permitted to challenge such authenticity at a later time upon a showing of good cause for failure to have filed such written objection.

(d) Samples, if otherwise admissible into evidence, may be displayed at the hearing and may be described for purposes of the record, or may be admitted in evidence as exhibits.

(e) Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to controvert such fact.

(f) The presiding officer shall file as exhibits copies of the following documents:

(1) The order to show cause or notice of hearing;

(2) Any notice of waiver or modification of rules made pursuant to § 316.44 or otherwise;

(3) Any waiver of hearing (together with any statement filed therewith) filed pursuant to § 316.49 or otherwise;

(4) The prehearing ruling, if any, made pursuant to § 316.55;

(5) Any other document necessary to show the basis for the hearing.

§ 316.60 Objections; offer of proof.

If any party in the hearing objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection without extended argument or debate thereon except as permitted by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made if a proper foundation has been laid for its admission. An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which the party contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form a copy of such evidence shall be marked for identification and shall accompany the records as the offer of proof.

§ 316.61 Exceptions to rulings.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action that he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 316.62 Appeal from ruling of presiding officer.

Rulings of the presiding officer may not be appealed to the Director prior to his consideration of the entire hearing, except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party or substantial detriment to the public interest. If an appeal is allowed, any party in the hearing may file a brief in quintuplicate with the Director within such period that the presiding officer directs. No oral argument will be heard unless the Director directs otherwise.

§ 316.63 Official transcript; index; corrections.

(a) Testimony given at a hearing shall be reported verbatim. The Bureau will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purpose. Any person desiring a copy of the transcript of the testimony and exhibits taken at the hearing or of any part thereof (except such materials as are described in § 301.04(b)) shall be entitled to the same upon application to the Hearing Clerk of the Bureau and upon payment of the costs thereof.

(b) At the close of the hearing, the presiding officer shall afford the parties and witnesses time (not longer than 30 days, except in unusual cases) in which to submit written proposed corrections of the transcript, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

§ 316.64 Proposed findings of fact and conclusions of law.

Any party in the hearing may file in quintuplicate proposed findings of fact and conclusions of law within the time fixed by the presiding officer. Any party so filing shall also serve one copy of his proposed findings and conclusion upon each other party in the hearing. The party shall include a statement of supporting reasons for the proposed findings and conclusions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of authorities relied upon.

§ 316.65 Report and record.

(a) As soon as practicable after the time for the parties to file proposed findings of fact and conclusions of law has expired, the presiding officer shall prepare a report containing the following:

(1) His recommended rulings on the proposed findings of fact and conclusions of law;

(2) His recommended findings of fact and conclusions of law, with the reasons therefor; and

(3) His recommended decision.

(b) The presiding officer shall certify to the Director the record, which shall contain the transcript of testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, and his report. Upon receipt of the certified record, the Director shall serve one copy of the report of the presiding officer upon each party in the hearing.

§ 316.66 Final order.

As soon as practicable after the presiding officer has certified the record to the Director, the Director shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Director finds that emergency conditions exist necessitating an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

§ 316.67 Copies of petitions for judicial review.

Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Director in quintuplicate. The Director shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals.

Subpart E—Seizure, Forfeiture, and Disposition of Property

AUTHORITY: The provisions of this Subpart E of Part 316 issued under secs. 501(b), 511, 1015, 84 Stat. 1271, 1276, 1277, 1278, 1291; 21 U.S.C. 871(b), 881, 965. Other statutory provisions interpreted or applied are cited to text in parentheses.

§ 316.71 Definitions.

As used in this subpart, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "custodian" means the officer required under § 316.72 to take custody of particular property which has been seized pursuant to the Act.

(c) The term "property" means a controlled substance, raw material, product, container, equipment, vessel, vehicle, or aircraft within the scope of the Act.

(d) The terms "seizing officer," "officer seizing," etc., mean any officer, authorized and designated by § 316.72 to carry out the provisions of the Act, who initially seizes property or adopts a seizure initially made by any other officer or by a private person.

(e) The term "Regional Director" means the Regional Director of the Bureau.

(f) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in § 301.02 of this chapter.

§ 316.72 Officers who will make seizures.

For the purpose of carrying out the provisions of the Act, all special agents of the Bureau are authorized and designated to seize such property as may be subject to seizure.

§ 316.73 Custody and other duties.

An officer seizing property under the Act shall store the property in a location designated by the custodian, generally in the judicial district of seizure. The Regional Directors are designated as custodians to receive and maintain in storage all property seized pursuant to the Act. The Regional Directors are also authorized to dispose of any property pursuant to the Act and any other applicable statutes or regulations relative to disposal, and to perform such other duties regarding such seized property as are imposed on the District Directors of the U.S. Bureau of Customs with respect to seizures under the customs laws.

(Sec. 605, 46 Stat. 754, 19 U.S.C. 1605; sec. 609, 46 Stat. 755, 19 U.S.C. 1609)

§ 316.74 Appraisement.

The custodian shall appraise the property to determine the domestic value at the time and place of seizure. The domestic value shall be considered the retail price at which such or similar property is freely offered for sale. If there is no market for the property at the place of seizure, the domestic value shall be considered the value in the principal market nearest the place of seizure.

(Sec. 606, 46 Stat. 754, 19 U.S.C. 1606)

§ 316.75 Advertisement.

(a) If the appraised values does not exceed $2,500, the custodian shall cause a notice of the seizure and of the intention to forfeit and sell or otherwise dispose of the property to be published once a week for at least 3 successive weeks in a newspaper of general circulation in the judicial district in which the seizure occurred.

(b) The notice shall: (1) Describe the property seized and show the motor and serial numbers, if any; (2) state the time, cause, and place of seizure; and (3) state that any person desiring to claim the property may, within 20 days from the date of first publication of the notice, file with the custodian a claim to the property and a bond with satisfactory sureties in the sum of $250.

(Sec. 607, 46 Stat. 754, as amended, 19 U.S.C. 1607)

§ 316.76 Requirements as to claim and bond.

(a) The bond shall be rendered to the United States, with sureties to be approved by the custodian, conditioned that in the case of condemnation of the property the obligor shall pay all costs and expenses of the proceedings to obtain such condemnation. When the claim and bond are received by the custodian, he shall, after finding the documents in proper form and the sureties satisfactory, transmit the documents, together with a description of the property and a complete statement of the facts and circumstances surrounding the seizure, to the United States Attorney for the judicial district in which the seizure was made for the purpose of proceeding to a condemnation of the property in the manner prescribed by law. If the documents are not in satisfactory condition when first received, a reasonable time for correction may be allowed. If correction is not made within a reasonable time the documents may be treated as nugatory, and the case shall proceed as though they had not been tendered.

(b) The filing of the claim and the posting of the bond does not entitle the claimant to possession of the property, however, it does stop the summary forfeiture proceedings. The bond posted to cover costs may be in cash, certified check, or on Treasury Department Form 171 with satisfactory sureties. The costs and expenses secured by the bond are such as are incurred after the filing of the bond including storage cost, safeguarding, court fees, marshal's costs, etc.

(Sec. 608, 46 Stat. 755, 19 U.S.C. 1608)

§ 316.77 Summary forfeiture.

If the appraised value does not exceed $2,500, and a claim and bond are not filed within the 20 days hereinbefore mentioned, the custodian shall declare the property forfeited. The custodian shall prepare the Declaration of Forfeiture and forward it to the Director of the Bureau of Narcotics and Dangerous Drugs as notification of the action he has taken. Thereafter, the property shall be retained in the custodian's district or delivered elsewhere for official use, or otherwise disposed of, in accordance with official instructions received by the custodian.

(Sec. 609, 46 Stat. 755, as amended, 19 U.S.C. 1609)

§ 316.78 Judicial forfeiture.

If the appraised value is greater than $2,500 or a claim and satisfactory bond have been received for property appraised at $2,500 or less, the custodian shall transmit a description of the property and a complete statement of the facts and circumstances surrounding the seizure to the U.S. Attorney for the judicial district in which the seizure was made for the purpose of instituting condemnation proceedings. The U.S. Attorney shall also be furnished the newspaper advertisements required by § 316.75.

(Sec. 610, 46 Stat. 755, 19 U.S.C. 1610)

§ 316.79 Petitions for remission or mitigation of forfeiture.

(a) Any person interested in any property which has been seized, or forfeited either summarily or by court proceedings, may file a petition for remission or mitigation of the forfeiture. Such petition shall be filed in triplicate with the Regional Director for the judicial district in which the seizure occurred. It shall be addressed to the Director if the property is subject to summary forfeiture pursuant to § 316.77, and addressed to the Attorney General if the property is subject to judicial forfeiture pursuant to § 316.78. The petition must be executed and sworn to by the person alleging interest in the property.

(b) The petition shall include the following: (1) A complete description of the property, including motor and serial numbers, if any, and the date and place of seizure; (2) the petitioner's interest in the property, which shall be supported by bills of sale, contracts, mortgages, or other satisfactory documentary evidence; and, (3) the facts and circumstances, to be established by satisfactory proof, relied upon by the petitioner to justify remission or mitigation.

(c) Where the petition is for restoration of the proceeds of sale, or for value of the property placed in official use, it must be supported by satisfactory proof that the petitioner did not know of the seizure prior to the declaration of condemnation of forfeiture and was in such circumstances as prevented him from knowing of the same.

(Secs. 613, 618, 46 Stat. 756, 757, as amended; 19 U.S.C. 1613, 1618)

§ 316.80 Time for filing petitions.

(a) In order to be considered as seasonably filed, a petition for remission or mitigation of forfeiture should be filed within 30 days of the receipt of the notice of seizure. If a petition for remission or mitigation of forfeiture has not been received within 30 days of the notice of seizure, the property will either be placed in official Government service or sold as soon as it is forfeited. Once property is placed in official use, or is sold, a petition for remission or mitigation of forfeiture can no longer be accepted.

(b) A petition for restoration of proceeds of sale, or for the value of property placed in official use, must be filed within 90 days of the sale of the property, or

within 90 days of the date the property is placed in official use.

(Secs. 613, 618, 46 Stat. 756, 757, as amended; 19 U.S.C. 1613, 1618)

§ 316.81 Handling of petitions.

Upon receipt of a petition, the custodian shall request an appropriate investigation. The petition and the report of investigation shall be forwarded to the Director. If the petition involves a case which has been referred to the U.S. Attorney for the institution of court proceedings, the custodian shall transmit the petition to the U.S. Attorney for the judicial district in which the seizure occurred. He shall notify the petitioner of this action.

(Sec. 618, 46 Stat. 757, as amended, 19 U.S.C. 1618)

Effective date. This order is effective on May 1, 1971. The Bureau anticipates that, as experience is gained in the administration of the Comprehensive Drug Abuse Prevention and Control Act and these regulations, these rules will necessarily be revised. The Director therefore invites public comment on these rules at any time, and such comments will be considered for amendatory purposes.

Dated: April 20, 1971.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

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